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Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

Chapter 01 ~~Certificate~~ Establishment of ~~Need for~~ and Other Actions Related to Health Care Facilities and Services

Authority: Health-General Article, §§19-109(a)(1) ~~and~~ 19-118(d), 19-120, 19-120.1, and 19-126, *et seq.*, Annotated Code of Maryland

10.24.01

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.01 Definitions.

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquisition" means:

(a) Any transfer of stock or assets that results in a change of the person or persons who control a health care facility; or

(b) The transfer of any stock or ownership interest in excess of 25 percent.

(2) "Adversely affected", for purposes of determining interested party status in a Certificate of Need review, as defined in §B(19) of this regulation, "means that a person:

(a) Is authorized to provide the same service as the applicant, in the same planning region ~~used for purposes of determining need under the State Health Plan, or in a~~ contiguous planning region if the proposed new facility or service could reasonably provide services to residents in the contiguous area, ~~and can demonstrate that the approval of the application;~~

~~(b) Can demonstrate that the approval of the application would~~

(i) ~~Would~~ materially affect the quality of care at a health care facility that the person operates, such as by causing a reduction in the volume of services when volume is linked to maintaining quality of care; ~~or~~

~~(ii)(e) Would suffer result in~~ a substantial depletion of essential personnel or other resources ~~by approval of at a health care facility that the application by the Commission person operates; or~~

~~(d)~~
(b) Can demonstrate to the reviewer that ~~a health care facility operated by~~ the person could suffer a potentially detrimental impact from the approval of a project before the Commission, in an issue area over which the Commission has jurisdiction, such that the reviewer, in the reviewer's sole discretion, determines that the person should be qualified as an interested party ~~to in the Certificate of Need review.~~

(3) "Aggrieved party" means:

(a) An ~~applicant or~~ interested party who-

~~(i) Presented has submitted written comments on an application to the Commission, both to the reviewer and in the form of exceptions to a proposed decision that is adverse to the position of that person, Commission and would~~

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~~(ii)~~ ⁴³ ~~Would~~ be adversely affected by the final decision of the Commission; or

⁴⁴ (b) The Secretary.

⁴⁵ (4) ~~"Ambulatory surgical surgery center" or "ASC" means any center, service, office, facility" means an entity, or part of an entity with two or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that:~~

⁴⁶ (a) ~~Has no more than two operating rooms that:~~

⁴⁷ (b) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

⁴⁸ (c) ~~Seeks reimbursement from payors for the provision of ambulatory surgical services. Subcategories of ASCs include: an ASC-P, which has only procedure rooms; an ASC-1, which has one operating room; and an ASC-2, which has two operating rooms.~~

⁴⁹ (5) ~~"Ambulatory surgical facility" means a health care facility or part of a health care facility with three or more operating rooms that:~~

⁵⁰ (a) ~~Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and~~

⁵¹ (b) ~~Seeks reimbursement from a third-party payor as an ambulatory surgical facility.~~

⁵² (6) ~~"Approved bed" means a bed approved by the Commission in a Certificate of Need, but not yet licensed.~~

⁵³ (7) ~~"Bed capacity" or "physical bed capacity" means the total number of beds that a health care facility can set up and staff in space designed for and licensable for use by patients requiring an overnight stay at the facility.~~

⁵⁴ (8) ~~"By or on behalf of" includes, but is not limited to, a capital expenditure which that affects the physical plant, service volume, or service capacity of a health care facility or health maintenance organization regardless of the source of the funds.~~

⁵⁵ (9) ~~"Capital expenditure" means:~~

⁵⁶ (a) An expenditure, including predevelopment costs, which:

⁵⁷ (i) Is made ~~as part of an acquisition, improvement, expansion, or physical plant replacement;~~

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(ii) Results in a change or relocation that would require a CON under Regulation .02A(2), (3), or (4) of this chapter; and

(iii) Is made by or on behalf of a health care facility, ~~and which, that~~ under generally accepted accounting principles, ~~is not properly chargeable as an expense of operation and maintenance, or which is made to obtain any physical plant for a facility by lease or comparable arrangement~~ ~~any physical plant for a facility;~~

~~(ii) Is made as part of an acquisition, improvement, or expansion, including redevelopment costs, and is more than the threshold for capital expenditures;~~

~~(iii) Is made as part of replacement of a physical plant of the health care facility and is more than the threshold for capital expenditures;~~

~~(iv) Results in a change in the bed capacity of a health care facility with respect to which the expenditure is made that meets the criteria of Regulation .02A(3) of this chapter;~~

~~(v) Results in a relocation of a health care facility that meets the criteria of Regulation .02A(2) of this chapter; or~~

~~(vi) Results in a change in the health care services to be offered by a health care facility that meets the criteria of Regulation .02A(4) of this chapter;~~

(b) A donation of a physical plant to a health care facility, if a Certificate of Need would be required for an expenditure by the health care facility to acquire the physical plant directly; or

(c) A transfer of a physical plant to a facility for less than fair market value, ~~which is considered a capital expenditure~~, if the transfer of the physical plant at fair market value would be a capital expenditure.

(8) "Center for Health Care Facilities Planning and Development" means that center in the Commission that acts as the entry and information point for applications for Certificate of Need (CON), requests for an exemption from Certificate of Need review, or other health care facility-related matters requiring action by the Commission, or its staff, as provided in this chapter.

(11) "Certificate of Conformance" means an approval issued by the Commission under Health-General § 19-120.1, Annotated Code of Maryland that allows an acute general hospital to establish emergency percutaneous coronary intervention (PCI) services or elective PCI services without a certificate of need.

(12) "Certificate of Need" or "CON" means an approval issued by the Commission for specified health care ~~project~~ projects under Health-General Article, Title 19, Annotated Code of Maryland.

(9) (13) "Certificate of Ongoing Performance" means an approval issued by the Commission that specific services meet standards evidencing continued quality under Health-General Article, § 19-120.1, Annotated Code of Maryland.

(14) "Commission" means the Maryland Health Care Commission.

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(15) "Comparative review" means a review in which two or more comparable CON applications submitted during the same review cycle are reviewed together and ranked based on each application's satisfaction of the CON review criteria.

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(16) "Department" means the Maryland Department of Health.

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(17) "Determination of coverage" means the written determination in accordance with Regulation .14A of this chapter whether CON or other Commission review is required for a project.

(18) "Existing health care facility" means a health care facility, as described in §B(12) of this regulation, which that is licensed by the Department.

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(11) "General hospice care program" means a coordinated, interdisciplinary program of hospice care services for meeting the special physical, psychological, spiritual, and social needs of dying individuals and their families, by providing palliative and supportive medical, nursing, and other health services through home-based or inpatient care during illness and bereavement.

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(19) "Executive Director" means the person appointed chief administrative officer of the Commission in accordance with Maryland Health-General Article, §19-106, Annotated Code of Maryland.

(20) "Freestanding medical facility" has the meaning set forth at Health-General Article, §19-3A-01, Annotated Code of Maryland

(21) "General hospice care program" has the meaning set forth at Health-General Article §19-901, Annotated Code of Maryland.

(22)

(19) Health Care Facility.

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(a) "Health care facility" means:

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(i) A hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

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(ii) A limited service hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

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(iii) A related institution, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

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(iv) An ambulatory surgical facility;

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(v) A rehabilitation facility;

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(v) An inpatient facility that is organized primarily to help in the rehabilitation of disabled individuals, through an integrated program of medical and other services provided under competent professional supervision;

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(vi) A home health agency, as defined in Health-General Article, §19-401(b);
Annotated Code of Maryland;

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(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

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(viii) A freestanding medical facility, as defined in Health-General Article, §19-3A-01, Annotated Code of Maryland;

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(ix) Except as provided by Regulation .03 and Health-General Article § 19-114(d)(2), Annotated Code of Maryland, a comprehensive care facility; and

(ix) Other health institutions, services, or programs that may be specified as requiring a ~~Certificate of Need~~ CON under State law.

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(b) "Health care facility" does not mean:

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(i) A hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts;

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~~(ii) For the purpose of providing an exclusion from a Certificate of Need under Health-General Article, §19-120, Annotated Code of Maryland, a facility to provide comprehensive care constructed by a provider of continuing care, as defined in Article 70B, Annotated Code of Maryland, if the facility is for the exclusive use of the provider's subscribers who have executed continuing care agreements except as provided by Regulation .03J of this chapter;~~

(ii)

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(iii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs; or

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(iii) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry.

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(23) "Health care project" means a health care project requiring a Certificate of Need as set forth in Regulation .02 of this chapter.

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(24) "Health care services" means clinically-related patient services.

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~~(15) "Health Facilities Coordination Office" means that office of the Commission which acts as the entry and information point for applications for Certificate of Need.~~

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(25) "Health maintenance organization" or "HMO" means a health maintenance organization under Health-General Article, §19-701, Annotated Code of Maryland.

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(26) "Health planning region" means the area used for ~~planning for~~ regulation of a particular service as provided in the State Health Plan.

(27) "Holder" means the applicant or applicants to whom the Commission awarded a Certificate of Need, an exemption from Certificate of Need, or other approval for a project that has not received first use approval nor, if necessary, a license from the Department for that project.

(28) Home Health Agency.

(a) "Home health agency" means a health-related organization, institution, or part of an institution that, directly or through a contractual arrangement, provides to a sick or disabled individual in the residence of that individual, skilled nursing and home health aide services, and ~~has the meaning set forth at least one other home health care service, that are centrally administered, as provided under~~ Health-General Article, §19-401, et seq. (b), Annotated Code of Maryland.

(b) "Home health agency" includes both parent (previously known as a branch) and subsidiary means a parent home health agency, as defined by the Centers for Medicare and Medicaid Services under 42 CFR §484.2.

(29) "Hospital capital threshold" means the lesser of 25 percent of the hospital's gross regulated charges for the immediately preceding year or \$50,000,000.

(30) Initiation of Construction.

(a) "Initiation of construction" for a new health care facility or expansion of an existing health care facility means that an approved project has ~~filed with the Commission appropriate documents and photographs establishing that the approved project has~~.

(i) Obtained all permits, approvals, or both considered necessary by applicable federal, State, and local authorities to initiate construction;

(ii) Completed all necessary preconstruction site work; and

(iii) Started the installation of the foundation system with placement of permanent components, such as reinforcing steel, concrete, and piles.

(b) "Initiation of construction" for the renovation of an existing health care facility means that an approved project has ~~filed with the Commission appropriate documents and photographs establishing that the approved project has~~.

(i) Obtained all permits, approvals, or both considered necessary by applicable federal, State, and local authorities to initiate renovation; and

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(ii) ~~Began~~ Started the demolition or relocation of affected services necessary to undertake the renovation project.

~~(20)~~
(31) "Interested party" means a person recognized by a reviewer as an interested party ~~and may include, including:~~

(a) ~~The Any~~ applicant ~~for who has submitted a proposed project; competing application in a comparative review;~~

(b) The staff of the Commission;
(c) ~~A third-party payor who can demonstrate substantial negative impact on overall costs to the health care system if the project is approved;~~

~~(d)~~
(c) A local health department in the jurisdiction or, in the case of regional services, in the planning region, in which the proposed facility or service is to be offered; ~~and~~

(d) In the review of a replacement acute general hospital project proposed by or on behalf of a regional health system that serves multiple contiguous jurisdictions, a jurisdiction within the region served by the regional health system that does not contain the proposed replacement acute general hospital project; and

(e) A person who ~~can demonstrate~~ has demonstrated to the ~~reviewer~~ Reviewer, that it meets the person would be definition of adversely affected, in an issue area over which the Commission has jurisdiction, by the approval of a proposed project.

~~(24)~~
(32) "Jurisdiction" means the 23 counties of Maryland and Baltimore City.

~~(22)~~
(33) Licensed Bed Capacity.

(a) "Licensed bed capacity" means the number of health care facility beds in any of the medical service categories or subcategories ~~in a health care facility identified in §B(25) of this regulation,~~ as they appear in the Commission's inventories of service capacity.

(b) ~~"Licensed bed capacity" does~~ "does" for acute general hospitals:

(i) Means the capacity authorized by the Secretary under Health-General Article, § 19-307.2, Annotated Code of Maryland;

(ii) Does not mean the number of holding beds to support hospital emergency services, bassinets, beds dedicated to observation of patients, an outpatient service, or recovery beds to support ambulatory surgical services.

~~(23)~~
(34) "Limited service hospital" means a health care facility that:

(a) Is licensed as a hospital ~~on or after January 1, 1999;~~

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(b) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;

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(c) Retains an emergency or urgent care center; and

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(d) Complies with the regulations adopted by the Secretary under Health-General Article, §19-307.1, Annotated Code of Maryland.

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⁽²⁴⁾
(35) "Long-term significant relationship" means a relationship characterized by mutual economic dependence, demonstrated by evidence such as a joint lease or mortgage or power of attorney, and evidence of common legal residence shown by driver's licenses, voter registration, or other identification.

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⁽²⁵⁾
(36) "Local health department" means the health department in a jurisdiction or a body designated by that jurisdiction to perform health planning functions.

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⁽²⁶⁾
(37) "Maryland Health Care Commission ~~(Commission)~~" means the agency established by Health-General Article, Title 19, Subtitle 1, Annotated Code of Maryland, ~~that replaced the Health Care Access and Cost Commission and the Maryland Health Resources Planning Commission, effective October 1, 1999.~~

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⁽²⁷⁾
(38) "Medical service" means:

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(a) Any of the following categories of health care services as they appear in the Commission's inventories of service capacity:

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(i) Medical/surgical/gynecological/addictions;

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(ii) Obstetrics;

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(iii) Pediatrics;

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(iv) Psychiatry;

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(v) Rehabilitation;

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(vi) Chronic care;

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(vii) Comprehensive care;

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(viii) Extended care;

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(ix) Intermediate care; ~~for alcohol and drug abuse withdrawal management and treatment, or for persons with intellectual disabilities; or,~~

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(x) Residential treatment center care; or

(b) A subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of medical services for which the State Health Plan provides a need projection methodology or specific standards.

⁽²⁸⁾
(39) "Merged asset system" is an entity comprised of one or more regulated health care facilities under common ownership.

(40) "Multiphased plan of construction" is a plan of construction for an addition, replacement, modernization, relocation, or conversion of an existing health care facility that involves distinct elements of construction, demolition, or renovation that require sequential implementation such that one element must be initiated before subsequent elements of the overall project can be initiated.

(a) Costs more than \$40,000,000; and

(b) Involves distinct elements of construction, demolition, or renovation that are initiated or completed before one or more subsequent elements of the overall project are initiated.

~~(29)~~(41) "Operating room" means a discrete area where sterile room in a surgical services are provided, as defined in the State Health Plan under COMAR 10.24.11 suite that meets the requirements of a restricted area and is designated and equipped for performing surgical operations or other invasive procedures that require an aseptic field.

~~(30)~~(42) "Other Commission approval" means approval of a Certificate of Conformance, Certificate of Ongoing Performance, or an exemption from CON review.

(43) "Participating entity" means a person recognized by the executive director Executive Director as a participating entity and may include:

(a) A third-party payor; including;

(i) An insurer or nonprofit health service plan that holds a certificate of authority and provides health insurance policies or contracts in Maryland;

(ii) A health maintenance organization that holds a certificate of authority in Maryland;

(iii) A union that is providing a health plan to union members on behalf of the employer in a jurisdiction in the health planning region that is used for purposes of determining need under the State Health Plan, where which the proposed project will be located or from which an existing health care facility seeks to relocate; and

(iv) A pharmacy benefit manager; and

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(v) A self-insured employer offering health benefits through the Employer Retirement Insurance Security Act of 1974.

(b) A municipality where the proposed project will be located or from which an existing health care facility seeks to relocate; or

(c) In the case of a hospital project, a local health department in a county that borders a county in which a proposed facility or service will be located.

(44) "Person" includes an individual, receiver, trustee, guardian, executor, administrator, fiduciary, or representative of any kind and any partnership, firm, association, limited liability company, limited liability partnership, public or private corporation, or other entity.

(45) Personal Physician.

(a) "Personal physician" means a physician licensed to practice medicine who:

(i) Was chosen by ~~the an~~ individual;

(ii) Has an established physician-patient relationship with the individual; and

(iii) Has provided health care services to the individual.

(b) "Personal physician" ~~may does not be mean~~ an owner, employee, a person under contract with, or ~~have who has~~ a material financial interest in the continuing care retirement community, its management company, or related entity.

(46) Predevelopment Costs.

(a) "Predevelopment costs" means all costs related to the preliminary development of a project, which include, but are not limited to, the costs of preliminary plans, studies, surveys, architectural designs, plans, reports, application fees, legal fees, financing fees, consulting fees, working drawings, or specifications undertaken in preparation for the development or offering of a health care project.

(b) "Predevelopment costs" does not include activities routinely undertaken by a health care facility as a part of its internal management or long-range planning process.

(47) "Primary service area" means:

(a) The Maryland postal ZIP ~~codes~~ code areas from which the first 60 percent of a hospital's patient discharges originate during the most recent 12-month period, where ~~the discharges from each ZIP code are ordered from largest to smallest number of discharges and where two or more ZIP codes have the same numbers of discharges, the ZIP codes are ordered from the largest to smallest based on the percentage of ZIP code discharges to the hospital in the most recent 12-month period;~~

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(i) The discharges from each ZIP code area are ordered from largest to smallest number of discharges; and

(ii) Two or more ZIP code areas having the same numbers of discharges are ordered from the largest to smallest based on the percentage of the hospital's discharges originating from the ZIP code area in the most recent 12-month period [are both included in the primary service area];

(b) Point ZIP codes physically within any of the ZIP ~~codes~~ code areas designated in §B(3347)(a) of this regulation;

(c) Maryland ZIP ~~codes~~ code areas physically contiguous to any of the ZIP codes designated in §B(3347)(a) of this regulation that provided 50 percent or more of their discharges to the hospital in the most recent 12-month period; and

(d) For a merged asset system, the ZIP ~~codes~~ code areas that are tabulated separately for each hospital, and all ZIP ~~codes~~ code areas identified for each hospital which are included in the primary service area of the merged asset system.

~~(35)"~~
(48) Public body obligation.

(a) "Public obligation" means a bond, note, evidence of indebtedness, or other obligation ~~for the payment of to repay~~ borrowed money issued by:

(i) The Maryland Health and Higher Educational Facilities Authority;

(ii) The State, or any agency, instrumentality, or public corporation of the State;

~~(e) Any public body as defined in Article 31, §9, Annotated Code of Maryland;~~

(iii) A governmental entity described in § 19-205(a) of the Local Government

Article;

(iv) The Mayor and City Council of Baltimore; or

(v) A municipal corporation ~~subject to~~;

(b) "Public obligation" does not include an obligation, or portion of an obligation, if:

(i) The principal of and interest on the ~~provisions of Article XI - Obligation or the portion of the Maryland Constitution~~ obligation is insured by an effective municipal bond insurance policy and issued on behalf of a hospital that voluntarily closed in accordance with § 19-120(l) of the Health-General Article; and

~~(36)~~

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(ii) the proceeds of the obligation or the portion of the obligation are used to finance wholly or partly, a facility or part of a facility that is used primarily to provide outpatient services at a location other than the hospital or that is used primarily by physicians who are not employees of the hospital to provide services to nonhospital patients.

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(49) "Rehabilitation facility" means an inpatient facility that:

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(a) Is organized for the primary purpose of assisting in the rehabilitation of persons with disabilities through an integrated program of medical and other services, which are provided under competent professional supervision;

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(b) Is licensed as a special rehabilitation hospital; and

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(c) Complies with the regulations adopted by the Secretary under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland.

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(50) "Religious order" means an incorporated, not-for-profit organization:

(a) That is owned or is wholly operated by an entity founded and operating for the sole purpose of carrying out religious precepts; and

(b) Whose members have taken the vows required by the order and have devoted their lives to religious service, to the exclusion of lay life and activities.⁽³⁷⁾

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(51) "Reviewer" means one Commissioner, appointed by the Executive Director of the Commission, who:

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(a) Evaluates each Certificate of Need application according to the entire record of written submissions and oral presentations by each applicant and interested party;

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(b) Prepares a proposed decision for the consideration of the full Commission; and

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(c) Serves as presiding officer at an evidentiary hearing on the application or applications, if the reviewer determines that an evidentiary hearing is warranted, according to the criteria set forth in Regulation 10D of this chapter.⁽³⁸⁾

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(52) "Secretary" means the Secretary of Health.⁽³⁹⁾

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(53) "State Health Plan" means the State Health Plan for Facilities and Services and its modifications or additions, adopted by the Commission pursuant to State health planning law, and incorporated by reference in this subtitle Maryland Health-General Article, § 19-118, Annotated Code of Maryland.

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(40) "Threshold for capital expenditures" means:

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~~(a) For a hospital, \$10,000,000 for the period June 1 through December 31, 2006, after that to be adjusted annually by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest \$50,000; and~~

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~~(e)~~ For a health care facility other than a hospital, \$5,000,000 for the period June 1 through December 31, 2006, after that to be adjusted by the Commission according to the Consumer Price Index - Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest \$50,000.

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.02 Coverage.

A. Except as provided in Regulations .03 ~~and~~ .04 ~~and~~ .05 of this chapter, a ~~Certificate of~~ ~~Need~~ **CON** is required before:

(1) A new health care facility is built, developed, or established;

(2) An existing health care facility is moved to another site, unless the relocation is:

(a) The result of a partial or complete replacement of an existing hospital or related institution, as defined in Health-General Article, §19-301, Annotated Code of Maryland, and is to another part of the site or immediately adjacent to the site of the existing hospital or related institution;

(b) Of an existing health care facility owned or controlled by a merged asset system, subject to the provisions of Regulation .03 ~~D~~ **03E** or .04A(2) of this chapter, whichever is applicable; or

(c) By a hospital converting to a limited service hospital, subject to the provisions of Regulation .04A(4) of this chapter, and is to a site within the immediate area, as determined by the Commission, as described in §B of this regulation;

(3) The bed capacity of a health care facility is changed, ~~unless the change in bed capacity:~~

(a) Is for a health care facility that is not an acute general hospital, does not exceed ten beds or 10 percent of the facility's total bed capacity, whichever is less;

(b) Would increase or decrease the bed capacity of an existing medical service provided by an acute general hospital, if:

(i) The total licensed bed capacity of the hospital does not increase;

(ii) The change is maintained for at least 1 year, unless modified pursuant to a Certificate of Need or exemption from Certificate of Need approved by the Commission, or the annual recalculation of hospital licensed bed capacity required at Health-General Article, §19-307.2, Annotated Code of Maryland; and

~~(iii) The hospital notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services;~~

~~(e) Is proposed pursuant to a merger or consolidation between health care facilities, and the Commission finds that the change:~~

~~(i) Is not inconsistent with the State Health Plan;~~

~~(ii) Will result in the delivery of more efficient and effective health care services;~~

~~and~~

~~(iii) Is in the public interest;~~

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~~(d) Is the result of the annual licensed bed recalculation for an acute general hospital provided under Health-General Article, §19-307, Annotated Code of Maryland;~~

~~(e) Is proposed for an acute general hospital in a jurisdiction with three or more acute general hospitals, and between acute general hospitals in a merged asset system located within the same jurisdiction, subject to the provisions of Regulation .03D(3) of this chapter; or~~

~~(f) Is proposed pursuant to Regulation .03C of this chapter, and meets the requirements of that subsection;~~

(4) The type or scope of any health care service offered by a health care facility is changed, and the change:

(a) Establishes a new medical service;

(b) Establishes a new ~~open heart~~ cardiac surgery, organ transplant surgery, burn treatment, or neonatal intensive care program;

(c) Establishes a new home health agency, general hospice care program, or freestanding ambulatory surgical facility;

(d) Builds or expands ~~ambulatory surgical capacity in any setting owned or controlled by a~~ hospital, if the building or expansion would increase the surgical capacity of the State's health care system; freestanding medical facility subject to rate regulation by the Health Services Cost Review Commission, or ambulatory surgical facility;

(e) Results in:

(i) The establishment of a new parent home health agency; or

(ii) ~~subunit by~~ The expansion of an existing home health agency;

~~(iii) The expansion of a home health agency into a jurisdiction in which it was not included in a previous Certificate of Need; or previously authorized by the Commission to operate.~~

~~(iii) A transfer of ownership of a subunit or a facility-based home health care service of an existing health care facility that separates the ownership of the subunit from the home health agency or home health care service that established the subunit;~~

(f) ~~Closes~~ Eliminates an existing medical service, ~~except as provided in Regulation .03 or .04 of this chapter, or is a temporary delicensure that meets the requirements of Regulation .03C of this chapter;~~

(g) Closes an existing health care facility or converts it to a non-health-related use, ~~with the exception of;~~

~~(i) The closure of an acute general~~

~~(ii) A hospital or its conversion to a limited service hospital, as provided in Regulation .03 or .04 of this chapter; or~~

~~(iii) The temporary delicensure of a health care facility that meets the requirements of Regulation .03C of this chapter;~~

(5) ~~A health care facility~~ A hospital makes a capital expenditure, as defined in Health-General Article, §19-120(k), Annotated Code of Maryland, and in this chapter, that exceeds the hospital

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~~capital threshold for capital expenditures, as adjusted for inflation as provided in this chapter,~~ including a capital expenditure:

(a) For the relocation of an existing health care facility owned or controlled by a merged asset system, except as provided in Regulation ~~.03H(3)~~03E of this chapter; and

(b) By ~~the~~a relocated health care facility to permit the facility to offer a new health care service for which ~~Certificate of Need~~CON is otherwise required.

B. Definition of Immediate Area for Limited Service Hospital Conversion.

(1) For the purpose of §A(2)(c) of this regulation, "immediate area" means a location on the site of the existing hospital, or on an adjacent site.

(2) A hospital may provide evidence as to why the Commission should approve a site for a limited service hospital beyond the immediate area of the converting hospital.

(3) The Commission ~~will~~shall not approve a site for a limited service hospital unless the site is ~~both~~within:

(a) A 5-mile radius of the site of the hospital proposing the conversion; and

(b) Its primary service area.

C. A person may not divide a project into component parts, except as permitted by this chapter. ~~The Commission staff shall, on request, issue a determination regarding whether two or more apparently individual projects actually represent component parts of a single project, considering factors such as, among other things, the timing of the projects, the functional areas of a facility to be affected, the number of construction contracts entered into, and whether expenditures under one contract depend upon the completion of a prior contract.~~

D. Proposed Change After Acquisition. If a person acquires an existing health care facility or service without a ~~Certificate of Need~~CON, in accordance with Regulation ~~.03A03~~ of this chapter, and proposes to change the health care services it provides or its bed capacity, the proposed change requires ~~Certificate of Need~~review and approval in accordance with §A of this regulation.

E. A health maintenance organization, or health care facility ~~that either controls, directly or indirectly, or is~~ controlled by an HMO or ~~a~~ group of HMOs, shall obtain a ~~Certificate of Need~~CON before it builds, develops, operates, or participates in building, developing, or operating:

(1) A hospital; ~~or~~

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- (2) ~~An ambulatory surgical facility; or~~
~~(2) Any other health care facility project for which a Certificate of Need~~ **CON** ~~is required~~
under §A of this regulation, ~~if that~~ **unless at least 90% of the patients who will receive**
~~health care facility is planned for or could~~ **services from the project will be used by non-subscribers of**
~~the individuals enrolled in that health maintenance organization or organizations.~~

~~F. Changes Not Covered By This Chapter. Changes to a health care facility not covered under §A of this regulation do not require Certificate of Need review and are not covered by this chapter. In instances when a person is uncertain whether the establishment of a new health care facility, or the expansion of an existing health care facility, is covered by Certificate of Need review requirements, the project requires, review for a determination of coverage under Regulation 14B of this chapter.~~

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03 Non-Coverage by Certificate of Need Review Requirements or Other Commission Approval.

A. Acquisition of an Existing Health Care Facility.

(1) At least 30 days before closing on a ~~contractual arrangement~~ contract to acquire a health care facility ~~that exists pursuant to a Certificate of Need or other authority recognized by the Commission,~~ the person acquiring the facility shall notify the Commission in writing, with a copy to the local health officer in each affected jurisdiction, of the intent to acquire the facility, and include the following information:

(a) The health care services provided by the facility;

(b) The bed capacity, or jurisdiction served, if a community-based service;

(c) ~~Complete data on admissions for~~ Organizational charts that include the health care facility prior calendar year to and after

~~(d) Gross operating revenue generated during the last fiscal year proposed acquisition; and~~

(e) (d) Any other information, as required in the applicable chapter of by these regulations, by the State Health Plan.

(2) ~~In an acquisition of a home health agency, the purchaser may only acquire the authority to offer home health agency services in jurisdictions in which chapter applicable to the health care facility, or requested by Commission records show that the facility being acquired either provided that service during fiscal year 2001, or was granted a Certificate of Need after that date.~~ Staff.

(3) ~~If the person acquiring the health care facility files timely and complete notice with the Commission under §A(1) of this regulation, and the Commission does not find within 30 days of receiving notice that the health care services, bed capacity, or jurisdictions served, if a community-based service, of the facility being acquired will change as a result of the acquisition, the Commission shall issue a written notice to the person, with a copy to the local health officer in each affected jurisdiction and to appropriate State and federal agencies, that Certificate of Need review is not required.~~

(4) ~~The notice of determination from the Commission that Certificate of Need review is not required is valid for 180 days.~~

(2) Except for a comprehensive care facility established under §H of this regulation, CON review is not required if Commission staff does not issue a determination of coverage within 30 days of receipt of timely and complete notice from the person acquiring the health care facility.

(3) Commission staff's determination that CON or other Commission review is not required may be issued with conditions, as appropriate, and remains valid for 180 days from its issuance. A new determination of coverage shall be required if the acquisition is not completed within that time period.

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~~(5)~~ If the acquisition is completed, ~~both the buyer and seller~~, shall sign a notice of completion of acquisition and file it with the Commission within 15 days of the completion of the acquisition.

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B. Acquisition of a Comprehensive Care Facility, Home Health Agency, or Hospice.

(1) In addition to providing the information in §A of this regulation, a person seeking to acquire a comprehensive care facility, home health agency, or hospice shall:

(a) Identify each person with an ownership interest in the acquiring entity or a related or affiliated entity, including

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(i) The percentage of ownership interest of each such person; and

(ii) The history of each such person's experience in ownership or operation of health care facilities;

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(b) Provide information on corporate structure and affiliations of the acquirer, purchase price, source of funds, and other relevant data as requested;

(c) Affirm that the services provided will not change as a result of the proposed acquisition and that its commitment to Medicaid participation will not decrease as a result of the proposed acquisition; and

(d) Affirm under penalties of perjury, that within the last ten years no owner or former owner of the purchaser, or member of senior management or management organization, or a current or former owner or senior manager of any related or affiliated entity has been convicted of a felony or crime, or pleaded guilty, nolo contendere, entered a best interest plea of guilty, received a diversionary disposition regarding a felony or crime, and that the purchaser or a related or affiliated entity has not paid a civil penalty in excess of \$10 million dollars that relates to the ownership or management of a health care facility.

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(2) Disqualification for Acquisition. A comprehensive care facility, home health agency, or hospice may not be acquired by an entity if an owner or member of senior management or an owner or member of senior management of a related or affiliated entity of the acquiring entity has been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime within the last ten years, unless:

(a) all of the individuals involved in the fraud or abuse are no longer associated with the entity or any of its related or affiliated entities;

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(b) each entity has fully complied with each applicable plan of correction; and

(c) if applicable, each entity has fully complied with each condition of the imposition of a civil penalty or agreed disposition.

(3) (6) Within 90 days of the completion of the acquisition, the buyer shall seek licensure or certification from the Office of Health Care Quality, as appropriate, or file a letter of intent under Regulation .02 of this chapter to relocate the health care facility. In an acquisition of a home health agency or hospice, the purchaser may only acquire the authority to provide services in jurisdictions for which the facility being acquired was granted a CON or is otherwise recognized by the Commission as having legal authorization.

C. (7) If the notice of the acquisition is not filed as required in § A of this regulation, or the Commission finds that acquisition of the facility will result in a change in health care services, bed capacity, or jurisdictions served, if a community-based service, the Commission shall issue written notice to the person seeking the acquisition that Certificate of Need review is required.

B. Closure of an Acute General Hospital a Health Care Facility.

(1) A Certificate of Need CON is not required to close an acute general hospital a health care facility or part of an acute general hospital in a jurisdiction with three or more acute general hospitals, or a health care facility, including a State hospital in any jurisdiction, if the hospital provides notice to the Commission at least 90 days prior to the closing or 45 days prior to the closing or partial closing and complies with the provisions of § B(2-4) of this regulation, if applicable.

(2) A Certificate of Need is not required to close an An acute general hospital or part of an acute general shall hold a public informational hearing in accordance with Regulation .04D if the hospital:

- (a) Files a notice of the proposed closing of the hospital with the Commission; or
- (b) Is located in a jurisdiction county with fewer than three acute general hospitals; if:

(and files a) At least 45 days before notice of the closing or partial closing of an acute general hospital, a notice of the proposed closing or partial closing is filed with the the hospital.

(3) The Commission, and, may require a health care facility not covered by § C(2) to hold a

(b) Within 30 days after the Commission receives notice of the hospital's intent to close, the hospital holds a public informational hearing in the jurisdiction where the acute general hospital is located, after consultation with the Commission to ensure that:

(i) Within 5 days of notifying the Commission of its intent to close, the hospital has provided public notice of the proposed closure and of the time and location of the required public informational information hearing, including publication in at least one newspaper of daily circulation in the affected area, and accordance with Regulation .04D.

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~~(ii) Information will be presented at the public hearing regarding continued access to acute care services in the affected area, and plans of the hospital, or the merged asset system that owns or controls the hospital, for retraining and placement of displaced employees and reuse of the physical plant.~~

~~(3)~~ Notice by the Commission to the Public, Elected Officials, and Other State Agencies:

~~(a) Within 5 days after it receives notice under this section that an acute general hospital intends to close, the Commission shall publish notice of its receipt in:~~

~~(i) At least one newspaper of daily circulation in the affected area, and~~

~~(ii) The next available issue of the Maryland Register.~~

~~(4) The Commission shall mail the same notice to elected public officials in whose district or county the hospital is located.~~

(4) If an acute general hospital that intends to close pursuant to this section has outstanding public body obligations issued on its behalf, written notification notice of its intended closing shall be given to the Maryland Health and Higher Educational Facilities Authority and the Health Services Cost Review Commission by the:

(a) Commission, within ~~5~~five days after receiving a written notification by the hospital of its intended closure;

(b) Hospital, within ~~10~~ten days of filing with the Commission its written notification of its intended closure, along with a written statement of all public body obligations issued on behalf of the hospital that provides the information required by the Economic Development Article ~~43C, §16A~~(g, § 10-346(a)(2), Annotated Code of Maryland; and

(c) Commission, that ~~at the~~ hospital in a jurisdiction with fewer than three acute general hospitals, held a public ~~information~~informational hearing in consultation with the Commission in the jurisdiction where the hospital is located.

D. Temporary Delicensure of Bed Capacity or a Health Care Facility.

(1) A temporary delicensure of licensed bed capacity or a licensed and operating health care facility does not require ~~Certificate of Need~~CON review, and the Commission will retain the bed capacity or health care facility on its inventory for up to ~~+one~~year, if the owner or licensed operator:

(a) Provides written notice to the Commission at least 30 days before the proposed temporary delicensure;

(b) Identifies good cause for the proposed temporary delicensure;

(c) States the intention either to bring the bed capacity back onto the facility's license or relicense the health care facility at the end of the ~~+one~~year period, or to notify the Commission that it intends to take another of the actions permitted under this subsection; and

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(d) Has received authorization from the Executive Director for the temporary delicensure.

(2) Bed capacity or a facility that has been authorized by the Commission to be temporarily delicensed is not subject to the provisions of this section:

(a) During the pendency at the Commission of a letter of intent to apply or an application for ~~Certificate of Need~~ CON approval involving the temporarily delicensed bed capacity or facility;

(b) If the Commission has issued a Certificate of Need to reimplement the facility's temporarily delicensed bed capacity, ~~and that Certificate of Need remains in good standing;~~

(c) If the Commission has ~~received and~~ approved a request pursuant to Regulation .03 or .04 of this chapter to reimplement the bed capacity or facility, and has determined that the bed capacity or facility may be reimplemented without ~~Certificate of Need approval~~ CON or other ~~finding by the~~ Commission approval, including but not limited to actions that may be undertaken by a merged asset system of which the facility is a member;

(d) If the Commission receives a notice of acquisition of the temporarily delicensed bed capacity or facility and the buyer and seller timely complete the acquisition, in accordance with Regulation ~~.03A03~~ .03 of this chapter; or

(e) If the Commission receives written notification that the owner or operator of the temporarily delicensed bed capacity or facility has applied for relicensure.

(3) The requirements and procedures in this subsection do not apply to a proposal to close, on either a temporary or a permanent basis:

(a) An acute general hospital or part of a hospital, including a medical service, in a jurisdiction with fewer than three acute general hospitals; or

(b) A health care facility that provides any medical service approved by the Commission as a regional or Statewide health resource.

(4) A health care facility ~~may~~ shall not request authorization by the Commission to temporarily delicense bed capacity or the entire health care facility more than one time in a 12- month period.

(5) No fewer than 30 days before the end of the 1-year or other applicable period, a health care facility that has temporarily delicensed bed capacity or its entire facility shall notify the Commission that, before the end of the 1-year or other applicable period, it will:

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(a) Apply to relicense the bed capacity or the entire facility temporarily delicensed pursuant to this subsection;

(b) Submit and receive the Executive Director's approval of a specific plan for the relicensure of the bed capacity or facility, that:

(i) Imposes stated time frames by which steps toward the relicensure of the bed capacity or facility will be accomplished, or the bed capacity or facility will be deemed abandoned, and

(ii) May be revised upon a proposal by the owner or operator, with the approval of the Executive Director;

(c) File a letter of intent, followed within 60 days by a Certificate of Need application, or request the applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter, for the relocation of the bed capacity or facility, or for a capital expenditure deemed necessary to relicense the temporarily delicensed beds or facility;

(d) Execute a binding contract to transfer ownership of the health care facility, if the requirements of §A of this regulation are met;

(e) Execute a binding contract to transfer ownership of the previously licensed bed capacity, contingent on the filing within 30 days of a letter of intent to apply for ~~Certificate of Need~~ CON approval, or other applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter if required, to relocate the bed capacity; or

(f) Relinquish the bed capacity, or seek the appropriate Commission approval to delicense and permanently close the health care facility.

(6) ~~For extraordinary cause shown, the~~ The Executive Director may extend the period of a temporary delicensure under this subsection beyond ~~one year, or the applicable time period.~~

~~(7) If bed capacity or a health care facility has been previously approved for temporary delicensure by the Commission:~~ good cause.

~~(7) (a) The time period provided under this subsection shall be deemed to expire 1 year from the date of the temporary delicensure, or 6 months from the effective date of these regulations, whichever is later; and An~~
~~(b) The affected health care facility shall comply with the provisions of §C(5) of this regulation before the expiration of the applicable time period.~~

~~(8) Notwithstanding the provisions of §C(7) of this regulation, an application for a Certificate of Need~~ CON ~~to reimplement at another location any previously operating bed capacity that has remained delicensed under this subsection~~ not operated for two or more years from the effective date

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~~of its removal from the facility's license, or from the closure of the entire facility,~~ shall demonstrate that the bed capacity ~~continues to be~~ is needed in the jurisdiction.

(8) If, at the end of the ~~one~~ one-year period or other time period permitted under this section, the requirements of §C(5) or (7) of this regulation have not been met, ~~and no~~ request for an extension of time has been granted pursuant to §C(6) of this regulation, and the previously delicensed bed capacity or facility has not been relicensed, the bed capacity or health care facility is deemed abandoned by its owner or operator. ~~The Commission shall issue a written notice to the owner of the affected facility, and to its licensed operator if the facility is not operated by its owner, of the opportunity to respond within 30 days before the abandonment is considered final, in order to demonstrate that the previously delicensed bed capacity or facility has been relicensed.~~

E. A Certificate of Need CON is not required to relocate an existing health care facility owned or controlled by a merged asset system, if:

(1) The proposed relocation is to a site in the primary service area of the health care facility to be relocated, as defined in the State Health Plan, and the relocation is not across jurisdictional boundaries;

(2) At least 45 days before the proposed relocation, notice is filed with the Commission, which will publish notice of the proposed relocation in the Maryland Register and a newspaper of ~~daily~~ general circulation in the affected area; and

(3) The relocation of the existing health care facility does not:

(a) Change the type or scope of health care services offered; and

~~(3) The relocation of the existing health care facility does not:~~

~~(a) Change the type or scope of health care services offered; and~~

(b) Require ~~In the case of a hospital, require~~ a capital expenditure ~~for its construction~~ that exceeds the hospital capital ~~review~~ threshold, ~~adjusted for inflation,~~ except as provided in §I of this regulation.

F. Change in Bed Capacity.

(1) A Certificate of Need CON is not required to ~~change the~~ increase or decrease bed capacity of a health care facility under the circumstances set forth in this section. if:

(2)

(c) For a health care facility that is not an acute general hospital, ~~2 years after its initial licensure or after its last change in~~ the change does not exceed ten beds or ten percent of the facility's total bed capacity, whichever is less, and the facility's licensed bed capacity has not changed in the preceding two years;

(b) ~~an existing~~ The change is proposed pursuant to a merger or consolidation between health care facilities, the hospital notifies the Commission ~~facility may request that~~ authorize an increase or decrease at least 45 days before the proposed change in bed capacity in the

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~~followingOf its medical services for which a health care facility shall obtain, and the Commission approval and seek licensure or certification from the Office of finds that the change:~~

~~(c) Is not inconsistent with the State Health Plan;~~

~~(ii) Will result in the delivery of more efficient and effective health care services;~~

~~and~~

Care Quality, if

~~(iii) Is in the increasepublic interest;~~

~~(c) For a special rehabilitation hospital or decrease in the total bed capacity of the facility, a residential treatment center, the change does not exceed ten beds or 10 percent, whichever is less;~~

~~(a) A health care facility, including an acute general hospital, may add ten beds or 40forty percent of theits current bed capacity, whichever is less, in any of the following medical services for which it must obtain separate licensure: and the facility's licensed~~

~~(i) Special rehabilitation hospital;~~

~~(ii) Special care units, as defined in COMAR 10.07.02.14.1 and .14.2;~~

~~(iii) Intermediate care; or~~

~~(iv) A residential treatment center, as defined in Health-General Article, §19-301(p), Annotated Code of Maryland; and~~

~~(b) A hospital classified as a general hospital pursuant to Health-General Article, §19-307, Annotated Code of Maryland, may not seek to increase its acute care bed capacity under this subsection. has not changed in the preceding two years;~~

~~(3) A Certificate of Need is not required before~~

~~(d) For an acute general hospital located in a jurisdiction with three or more acute general hospitals increases or decreases its bed capacity, if, the change:~~

~~(a) Occurs on or after July 1, 2000;~~

~~(b)~~

~~(i) Is between hospitals in a merged asset system located within the same health planning region;~~

~~(c)~~

~~(ii) Does not involve comprehensive care or extended care beds;~~

~~(iii)(d) Does not occur earlier than 45 days after a notice of intent to reallocate bed capacity is filed with the Commission; and~~

~~(iv)(e) Does not create a new health care service through the relocation of beds from one jurisdiction to another jurisdiction pursuant to this subsection.~~

~~(4) A Certificate of Need is not required if the increase or decrease~~

~~(e) The change in bed capacity is the result of the annual recalculation of licensed bed capacity in acute general hospitals provided for under Health-General Article, §19-307.2, Annotated Code of Maryland;~~

~~(f) (5) A Certificate of Need is not required to increase or decrease the bed capacity of For an existing medical service as provided by an acute general hospital, if;~~

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(i) ~~(e)~~ The total bed capacity of the hospital does not increase;

(ii) ~~(f)~~ The change is maintained for at least ~~+a one-year period~~, unless modified pursuant to ~~a Certificate of Need~~ CON, or exemption from ~~Certificate of Need approved by the Commission~~ CON, or ~~as a result of~~ the annual recalculation of hospital licensed bed capacity required ~~by~~ at Health-General Article, §19-307.2, Annotated Code of Maryland; and

(iii) ~~(g)~~ The hospital notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services.

(g) At least 45 days before increasing or decreasing bed capacity, written notice of the intent to change bed capacity is filed with the Commission, and the increase or decrease in bed capacity will occur in:

(i) ~~An existing general hospice that has a current license issued by the Secretary and involves an increase in bed capacity for the provision of inpatient hospice care under the facility's current license; or~~

(ii) ~~F. An existing intermediate care facility that offers residential or intensive substance-related disorder treatment services for withdrawal management and treatment under the facility's current license issued by the Secretary.~~

(2) Except as otherwise provided in this regulation, a CON is not required to decrease bed capacity at a health care facility if at least 45 days before decreasing bed capacity, written notice of the intent to change bed capacity is filed with the Commission.

G. A CON is not required for a non-hospital health care facility project by a health maintenance organization ~~is not required to obtain a Certificate of Need for a health care project that is planned for and will be used exclusively by the subscribers of that if:~~

(a) At least 90% of the patients who will receive health care services from the facility are enrolled in the health maintenance organization;

(b) ~~other than those set forth in Regulation .02 of this chapter, although notice to the Commission is required. This notice shall consist of the type~~ The health maintenance organization requests a determination of the coverage from Commission staff that describes its proposed project, location of the project (including its street address), a brief description of services to be offered, and an initial estimate of the number of members, and the health care service to be served by the project provided; and

(c) Commission staff issues a determination, with or without conditions, that CON or other Commission review is not required.

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~~H.~~ A home health agency is not required to obtain a ~~Certificate of Need~~ CON to open a branch office ~~(previously called a satellite office),~~ as defined by ~~the~~ Centers for Medicare and Medicaid Services at 42 CFR §484.2, although notice to the Commission is required.

~~H.~~
~~L.~~ Religious Orders.

(1) A ~~Certificate of Need~~ CON is not required before a religious order seeks licensure to operate a comprehensive care facility for the exclusive use of members of that religious order, provided that the religious order seeks and receives a determination of coverage from Commission staff that a CON is not required.

(2) For the purpose of this section, "religious order" means an incorporated, not-for-profit organization: ~~(a) That is, or is wholly operated by, an entity founded and operating for the sole purpose of carrying out religious precepts; and~~

~~(b) Whose members have taken the vows required by the order and have devoted their lives to religious service, to the exclusion of lay life and activities.~~

(3) At least 45 days before a religious order submits to the Department a ~~The~~ request for licensure for a comprehensive care facility, the religious order shall submit a written request for ~~a~~ determination of non-coverage by Certificate of Need review requirements, as described in Regulation 14B of this chapter. The request shall provide the following information:

(a) The name and address of the facility;

(b) The number of beds in the facility;

(c) The name of the religious order that will own and operate the facility;

(d) ~~Assurance~~ An affirmation that the ~~comprehensive care~~ facility will be owned and operated by the religious order for the exclusive use of its members; and

(e) Agreement to participate in the Maryland Long-Term Care Survey, as authorized by COMAR 10.24.03.

(3) ~~(4) The~~ Commission staff shall issue a determination under §H(3) of this regulation within 15 working days of receipt of the information required in that subsection.

~~I. Capital Expenditure, either CON review~~

~~(1) A Certificate of Need is not required before a health care facility makes a capital expenditure that exceeds the Certificate of Need review threshold for capital expenditures as adjusted for inflation, under the circumstances described in this section.~~

(2) A Certificate of Need is not required before a health care facility makes a capital expenditure for:

(a) Site acquisitions; with

(b) The acquisition of a health care facility, if the provisions of §A of this regulation are met;

~~(c) Business or office equipment not directly related to patient care, including health care clinical information systems; without conditions, or that CON review is required for stated reasons.~~

(d) The acquisition and installation of major medical equipment.

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~~(2)~~ A Certificate of Need is not required by a hospital or a nursing home before a capital expenditure for equipment, construction, or renovation that is not directly related to:

~~(a) Patient care; and~~

~~(b) Any change in patient charges or other rates.~~

J. Hospital Capital Expenditures in Excess of the Hospital Capital Threshold.

(1) A ~~Certificate of Need~~ CON is not required by a hospital before it obligates an amount exceeding the ~~review~~ hospital capital threshold for capital ~~expenditure~~ expenditures for physical plant construction or renovation, or before it receives a donated physical plant whose appraised value exceeds the ~~review~~ hospital capital threshold, under the following circumstances:

(a) The capital expenditure may be related to patient care;

(b) The capital expenditure does not require, over the entire period or schedule of debt service associated with the project or plant, a total cumulative increase in patient charges or hospital rates of more than \$1,500,000 for the capital costs associated with the project;

(c) At least 45 days before an obligation is made or the physical plant is donated, the hospital provides notice to the Commission and to the Health Services Cost Review Commission, in the form of a written request for determination of coverage, as provided in Regulation ~~14B 14A~~ of this chapter, which shall contain the following ~~relevant financial~~ information:

(i) A description of the proposed capital project, including whether it involves new construction, renovation of or additions to the existing physical plant, or the donation of a physical plant, with any necessary adaptations;

(ii) The total capital costs associated with the project;

(iii) The sources and uses of funds to be applied to the project, including hospital equity contributions, if applicable, as documented by audited financial statements of the hospital and relevant subsidiary corporations, if any, from which funds are to be taken;

(iv) A description of the financing arrangement, if applicable, for the proposed project, including the debt service schedule; and

(v) A statement by one or more persons authorized to represent the hospital that the hospital does not require a total cumulative increase in patient charges or hospital rates of more than \$1,500,000 for the capital costs associated with the project.

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(2) After consultation with the Health Services Cost Review Commission, the Commission shall issue a determination ~~that Certificate of Need~~ whether CON review is ~~not~~ required within 45 days after it receives the information specified in this section.

~~(2) If the Commission has~~ Staff does not ~~made the financial~~ issue a determination within 60 days of receipt of ~~the~~ all relevant financial information by the Commission and by the Health Services Cost Review Commission, the Commission is considered to have issued a determination ~~of noncoverage~~ that approval of the capital expenditure is not required by the Commission or by the Health Services Cost Review Commission.

(3) Commission staff shall issue a determination that either CON review is not required, with or without conditions, or that CON review is required for stated reasons.

K. Continuation of Specific ~~Exclusion~~ Exception from Certificate of Need for Continuing Care Retirement Communities.

(1) ~~The~~ A comprehensive care facility on the campus of a continuing care retirement community is excepted from CON review provided that the requirements of Health-General Article §19-114(d)(2)(ii)(1), Annotated Code of Maryland and this chapter, are met and the number of comprehensive care beds ~~excluded from Certificate of Need requirements and~~ located on the campus of ~~the~~ continuing care retirement community ~~may~~ does not exceed:

(a) 20 percent of the number of independent living units at a continuing care retirement community that has 300 or more independent living units;

(b) 24 percent of the number of independent living units at a continuing care retirement community that has fewer than 300 independent living units.

(2) ~~Limited Direct Admission.~~ Notwithstanding the provisions of Health-General Article, §19-114(d)(2)(ii), Annotated Code of Maryland, ~~and Regulation .01B(12)(b)(ii) of this chapter,~~ a continuing care retirement community does not lose its ~~exclusion~~ exception from ~~Certificate of Need~~ CON when the continuing care community admits an individual directly to a comprehensive care facility within the continuing care community under either of the following circumstances:

(a) Two individuals having a long-term significant relationship are admitted together to a continuing care retirement community and:

- (i) The admission occurs after October 1, 1999;
- (ii) The admission includes spouses, two relatives, or two individuals having a long-term significant relationship, as defined in Regulation .01B of this chapter and supported by documentary proof in existence for at least ~~one~~ one year before application to the continuing care retirement community, admitted at the same time, under a joint contract, who are jointly responsible for expenses incurred under the joint contract; and

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▲ (iii) One of the individuals admitted under the joint contract will reside in an independent living unit or an assisted living unit; or

▲ (b) An individual is admitted directly into a comprehensive care bed at a continuing care retirement community and:

▲ (i) The individual must have executed a continuing care agreement and must have paid entrance fees that are at least equal to the lowest entrance fee charged by the continuing care retirement community for its independent or assisted living units;

▲ (ii) The individual must pay the entrance fee by the same method, terms of payment, and time frame as a person who immediately assumes residence in an independent or assisted living unit at that continuing care retirement community; and

▲ (iii) The individual admitted to the comprehensive care bed must have the potential for eventual transfer to an independent living unit or assisted living unit at that continuing care retirement community, as determined by the subscriber's personal physician, as defined in Regulation .01B of this chapter.

▲ (3) Under §~~K~~J(2)(b)(iii) of this regulation, an individual is deemed not to have potential for eventual transfer to an independent living unit or assisted living unit if the individual can qualify for hospice services under federal Medicare regulations or if the individual has an irreversible condition that would make it unlikely that the individual could transfer to an independent living unit or assisted living unit at the continuing care retirement community. Irreversible conditions include quadriplegia, ventilator dependence, and any end-stage condition.

▲ (4) The total number of comprehensive care beds occupied by individuals who are directly admitted to comprehensive care beds pursuant to §K(2)(b) of this regulation may not exceed 20 percent of the total number of licensed and available comprehensive care beds at the continuing care retirement community.

▲ (5) The admission of the individual directly into the comprehensive care bed pursuant to §~~K~~J(2)(b) of this regulation may not cause the occupancy of the comprehensive care facility at the continuing care retirement community to exceed 95 percent of its current licensed capacity.

▲ (6) ~~Before admitting an individual directly into a comprehensive care bed pursuant to §K(2)(b) of this regulation, the nursing home administrator of the~~The comprehensive care facility at the continuing care retirement community shall ~~keep on file a statement, in a format required by the Commission and signed~~maintain an attestation by the individual's personal physician, ~~that the individual has~~ the potential for eventual transfer to an independent living unit or an assisted living unit.

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(7) The nursing home administrator of the comprehensive care facility at each continuing care retirement community who admits an individual directly to a comprehensive care bed under this section shall ~~submit~~maintain information ~~quarterly to, in a format specified by~~ the Commission, about each admission. ~~The information shall be submitted within 30 days after the end of the reporting period,~~ in the format required by the Commission and encrypted by the continuing care retirement community so that the individual's identity will not be disclosed. ~~Information submitted~~The forms shall be maintained by the nursing home administrator, to be provided to Commission staff upon its request, and shall include:

(a) The number and utilization of licensed comprehensive care beds excluded from Certificate of Need requirements at the continuing care retirement community;

(b) The admission source of each individual admitted pursuant to §~~K~~J(2)(b) of this regulation to a comprehensive care bed excluded from Certificate of Need requirements at the continuing care retirement community;

(c) For an individual admitted pursuant to §~~K~~J(2)(b) of this regulation, the amount of and terms of payment for the entrance fee;

(d) The dates of admission and discharge of each individual admitted pursuant to §~~K~~J(2)(b) of this regulation;

(e) The site to which an individual directly admitted pursuant to §~~K~~J(2)(b) of this regulation is discharged; and

(f) Any other information as required by ~~the Commission staff~~.

~~(8) A continuing care retirement community that admits an individual to a comprehensive care bed pursuant to §K(2)(b) of this regulation shall maintain documentation required by §K(6) of this regulation and documentation underlying the information submitted under §K(7) of this regulation and make the documentation available to the Commission upon request.~~

~~(9) Unless the conditions of §K(2)(a) or (b) of this regulation are met, the provisions of Health General Article, §19-114(d)(2)(ii), Annotated Code of Maryland, apply; that is, a person may not be directly admitted to a CON-excluded nursing home bed of a continuing care retirement community.~~

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.04 Exemption from Certificate of Need Review.

A. ~~Subject to the procedural requirements of this regulation, the~~ The Commission may exempt from the requirement of ~~Certificate of Need~~ CON review and approval the following actions ~~proposed by a health care facility or merged asset system comprised of two or more health care facilities;~~

(1) Merger or consolidation of two or more hospitals or other health care facilities, if the facilities or an organization that operates the facilities give the Commission 45 days written notice of their intent to merge or consolidate;

(2) Relocation of an existing health care facility owned or controlled by a merged asset system, if:

(a) The relocation is to a site outside the primary service area of the health care facility to be relocated but within the primary service area of the merged asset system; and

(b) The relocation of the existing health care facility does not:

(i) Change the type or scope of health care services offered; and

(ii) Does not require a capital expenditure for its construction that exceeds the capital review threshold, adjusted for inflation, except as provided by Regulation ~~.03#03J~~ of this chapter;

(3) A change in the bed capacity of an existing health care facility pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a facility to a ~~nonhealth~~ non-health-related use, except as provided in Regulation .03I of this chapter;

(4) A change in the type or scope of the health care services offered by a health care facility, if, at least 45 days before increasing or decreasing the volume of one or more health care services, the Commission ~~in its sole discretion~~ finds that the proposed change is pursuant to the:

(a) Consolidation or merger of two or more health care facilities;

(b) Conversion of all or part of a health care facility to a non-health-related use; or

(c) Conversion of a hospital to a limited service hospital;

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C. Notice by the Commission to the Public, Elected Officials, and Other State Agencies.

(1) Within ~~five~~ days after it receives a complete Notice of Intent from a health care facility seeking exemption from ~~Certificate of Need~~ CON review, the Commission shall publish notice of its receipt ~~in~~:

(a) At

(a) ~~In at~~ least one newspaper of ~~daily~~ general circulation in the affected area; and

(b) ~~The~~ In the next available issue of the Maryland Register; and

(c) On the Commission's website;

(2) The Commission shall mail the same notice to elected public officials in whose district or jurisdiction the exemption from ~~Certificate of Need~~ CON review is proposed.

(3) The Commission shall solicit comment ~~and relevant information~~ from the affected public, in evaluating whether the action or project proposed for exemption from ~~Certificate of Need~~ CON review is in the public interest.

(4) If a hospital that intends to close or to convert to a limited service hospital has outstanding public body obligations issued on its behalf, written notification of intended closure or conversion shall be given to the Maryland Health and Higher Educational Facilities Authority and the Health Services Cost Review Commission by the:

(a) Commission, within 5 days after receiving a written notification by the hospital of intended closure or conversion, that it has received the hospital's notification and begun its review of the information provided pursuant to §B of this regulation;

(b) Hospital, within 10 days of filing with the Commission its written notification of intended closure or conversion, along with a written statement of any public body obligations issued on behalf of the hospital that provides the information required by Article 43C, §16A(g), Annotated Code of Maryland; and

(c) Commission, not later than 150 days before the scheduled date of the hospital's closure, that it has made the finding required by §E of this regulation.

D. Public Informational Hearing.

(1) ~~Within 30 days of filing a notice of intent to seek exemption from Certificate of Need review,~~ An acute general hospital shall hold a public informational hearing ~~shall be held in the jurisdiction~~ county where ~~an acute general hospital or a State hospital it is located that intends~~ within 30 days after it has filed with the Commission notice of its intent to:

(a)

(a) ~~Close or~~;

(b) partially close, if the hospital is located in a jurisdiction with fewer than three acute general hospitals; or

(c)

(c) Convert to a limited service hospital ~~- or freestanding medical facility.~~

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(2) Before holding the public informational hearing, the hospital shall consult with the Commission, to ensure that:

(a) Within ~~five~~ days of notifying the Commission of its intent to close, ~~partially close, or convert,~~ the hospital has provided public notice of the proposed closure ~~or conversion~~ and of the time and location of the required public informational hearing ~~and how the public can electronically obtain additional information,~~ including publication in at least one newspaper of ~~daily~~ general circulation in the affected area; and

(b) ~~Information will be presented at the~~ The public hearing ~~regarding continued access to acute care or other services in~~ will address the information required by § D(3)

(3) affected area, and plans of the Requirements for a public informational hearing.

(a) ~~The acute general hospital, or the merged asset system that owns,~~ proposing to close, partially close, or convert to a limited service hospital or freestanding medical facility shall hold a public informational hearing at the hospital or if that is not feasible at a public meeting area near the hospital;

(b) The hospital shall post a notice of the public informational hearing in public areas of its facility and on the landing page of its website;

(c) The hospital shall identify to the public the names of the senior management and Board of Directors attending the meeting;

(d) The hospital shall present at least the following information at the public informational hearing:

(i) The reasons for the closure, partial closure, or conversion;

(ii) The plan for transitioning acute care services previously provided by the hospital to residents of the hospital service area;

(iii) The plan for addressing the health care needs of the residents of the hospital service area;

(iv) The ~~plan~~ for retraining and ~~placement of~~ placing displaced employees and reuse of;

(v) The plan for the hospital's physical plant- and site; and

(vi) The proposed timeline for the closure, partial closure, or conversion to a freestanding medical facility.

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(e) The public informational hearing shall be recorded; and

~~(f) E.~~ Within ten business days after the public informational hearing, the hospital shall make available on its website a recording of the public informational meeting and provide a written summary of the hearing, which shall also be provided to:

(i) The Governor;

(ii) The Secretary;

(iii) The governing body of the county in which the hospital is located;

(iv) The local health department and the local board of health or similar body for the county in which the hospital is located;

(v) The Commission; and

(vi) Subject to § 2-1257 of the State Government Article, the Senate Finance Committee, the House Health and Government Operations Committee, and the members of the General Assembly who represent the district in which the hospital is located.

E. Unless otherwise provided in this chapter for a specific type of health care facility, the Commission shall issue a determination of an exemption from Certificate of Need CON review to the health care facility or the merged asset system seeking this determination within 45 days after it receives the notice of intent required by §B of this regulation, if:

(1) The facility or system has provided the information required by the notice of intent, and has held a public informational hearing if required by §D of this regulation; and

(2) The Commission, in its sole discretion, finds that the action proposed:

~~(a) Is in the public interest;~~

~~(b)~~

(a) Is not inconsistent with the State Health Plan or an institution-specific plan developed by the Commission under Health-General Article, §19-119, Annotated Code of Maryland; and

~~(b)~~ Will result in more efficient and effective delivery of health care services; and

(c) Is in the public interest.

F. Freestanding Medical Facility.

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(1) In accordance with COMAR 10.24.19.04C and this regulation, the Commission may exempt from CON review the establishment of a freestanding medical facility as a result of a conversion from a licensed acute general hospital.

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(2) At least 60 days before the conversion, written notice of intent to convert the licensed general hospital to a freestanding medical facility must be filed with the Commission in accordance with COMAR 10.24.19.04C.

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(3) Provided that all the requirements of this regulation and COMAR 10.24.19.04C are met, the Commission shall grant the exemption if it finds, in its sole discretion, that the conversion:

(a) Is consistent with the State health plan;

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(b) Will result in the delivery of more efficient and effective health care services;

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(c) Will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system as determined by the State Emergency Medical Services Board; and

(d) Is in the public interest.

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(4) The Commission may approve, approve with conditions, or deny the requested exemption.

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(5) Failure to maintain compliance with the requirements of the State Health Plan, with conditions on an exemption, or with the timeframe for completion of the conversion shall result in withdrawal of the exemption issued by the Commission in accordance with Regulation .12.

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10.24.01.05 Ambulatory Surgical Facilities, Surgery Centers: Determination of Coverage and Data Reporting.

A. Determination of Coverage by Certificate of Need.

~~(1) Determination of Coverage. A Certificate of Need~~ **CON** ~~is not required for any an ambulatory surgery center, service, office, facility, or office of one or more health care practitioners or a group practice, as defined in Health Occupations Article, Title 1, Annotated Code of Maryland, if,~~

~~(2) A person shall obtain a determination of coverage from the entity does not have more than one~~ **Commission before:**

~~(a) establishing a new ambulatory surgery center;~~

~~(b) adding a new, operating room- or any other rooms in which procedures are performed to an existing ambulatory surgery center; or~~
~~(2)~~

~~(c) making any change in the information provided for initial determination of coverage.~~

~~(3) Change in Location. A determination of coverage letter for an office with ambulatory surgery capacity center is issued only for the exact address specified. in the determination. A change in address or in the layout of the center before the office it is built, developed, or established requires a new determination of coverage.~~

~~(3)~~
~~(4) Change in Ownership. A determination of coverage letter for regarding an ambulatory surgery capacity center is issued only for the person specified. A new in the determination of coverage will be required if. If the principal owner or a majority of other owners changes, of an existing ambulatory surgery center is expected to change, a request for a new determination of coverage shall be filed and include;~~

~~(4) Expiration Date~~

~~(a) A complete list of the existing owners and the post-transaction owners; and~~

~~(b) Coverage Determination Letter. A- An attestation by the ambulatory surgery center that, subsequent to the issuance of the original determination of coverage letter for new freestanding, no changes have been and that, as a result of the planned change in ownership, no changes will be made;~~

~~(i) To the physical plant or layout of the ambulatory surgery center; or~~

~~(ii) In the surgical specialties provided.~~

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(5) Expiration of Determination of Coverage. A determination of coverage for a new ambulatory surgery center or for new capacity at an existing ASC-P or ASC-I may be issued with conditions and is effective for two years from the date of the letter determination. If that capacity is not built, developed, or established within two years, that letter of the determination of coverage is void.

(6) Notice.

(a) Before seeking to establish a new operating room or any other rooms in which procedures are performed, or making to make any change in the information provided for initial determination of coverage by Certificate of Need, a person shall provide notice to the Commission at least 45 days in advance that includes all information required by COMAR 10.24.11.04A.

(b) The notice shall include the intended start-up date of the proposed ambulatory surgical services at the specified location.

(7)

(e) The notice shall provide the following information:

(i) The name and address of the entity seeking to provide ambulatory surgical services, and the location where these services will be provided;

(ii) A statement that the operating room or rooms will meet the requirements relating to quality of care and patient safety necessary to obtain Medicare certification or State licensure, whichever is appropriate, for life and fire safety, control of infection, quality assessment and improvement, patient transfer, credentialing, and medical record keeping, with documentation of having received licensure or certification, as appropriate, to be submitted in the next annual data survey conducted by the Commission;

(iii) The number of operating rooms at the location, and a drawing or plans showing the location and dimensions of each proposed operating room and other rooms in the office;

(iv) The names of each person and organization with an ownership interest in the entity, and its officers, directors, partners, and owners;

(v) The names of any other ambulatory surgical facilities in which individuals listed in response to §A(5)(c)(iv) of this regulation have an interest or other economic relationship, as an officer, director, partner, member, or owner;

(vi) A listing of each other ambulatory surgical facility at the same address;

(vii) Contractual relationships to provide ambulatory surgical services between the entity and other health care facilities or health care providers who are not employees of the entity, or exercise only medical practice privileges at the location; and

(viii) The names and specialties of each health care practitioner who will perform surgical services at the facility and the general types of surgery to be performed there.

(6) For purposes of this regulation, all ambulatory surgery centers, services, offices, facilities, or offices of one or more health care practitioners or a group practice primarily providing ambulatory surgical services that are located in the same building and that share any common ownership or control shall be considered one entity, and their operating rooms shall be considered together for purposes of determining coverage under Regulation .02 of this chapter, or this regulation.

(7) The office of one or more health care providers or a group practice performing ambulatory surgical services with two operating rooms may be exempt from Certificate of Need requirements if the Commission, in its sole discretion, determines that:

(a) A second operating room is necessary to promote the efficiency, safety, and quality of the surgical services offered; and

(8) A CON

(b) The office meets the criteria for exemption from Certificate of Need review as an ambulatory surgical facility set forth in the State Health Plan under COMAR 10.24.11.

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~~(8) Except as provided in this regulation or permitted in the Certificate of Need or exemption criteria in the State Health Plan under COMAR 10.24.11, an ambulatory surgical facility or other entity primarily providing ambulatory surgical services may not relocate beyond an adjacent site or expand its number of operating rooms after June 1, 1995, without obtaining a Certificate of Need.~~

~~(9) A Certificate of Need~~ is not required for ambulatory surgical services provided as part of an office of one or more individuals licensed to practice dentistry under Health-Occupations Article, Title 4, Annotated Code of Maryland, for the purpose of practicing dentistry, if the ambulatory surgical facility is not used in a medical practice other than dentistry.

B. Data Reporting and Annual Survey of Ambulatory Surgical ~~Centers,~~ Facilities, and Providers.

~~(1) To provide information for the Commission's planning purposes and to determine changes in circumstances and operation that may affect coverage by Certificate of Need~~ CON requirements, ~~each existing providers in offices or facilities~~ ambulatory surgery center, facility, office, and provider that primarily ~~providing~~ provides ambulatory surgical services shall ~~provide~~ annually provide to the Commission the information required by COMAR 10.24.04.

~~(2) A person providing ambulatory surgical services who is required to obtain a license under Health-General Article, §19-3B-02(a), Annotated Code of Maryland, shall annually provide the required information on a form provided by the Commission.~~

~~(3) The information to be provided includes the following:~~

~~(a) The information listed in §A(5) of this regulation, only if there have been any changes in this information during the reporting period;~~

~~(b) Cost, charge, and reimbursement data, including the amount of care reimbursed by Medicaid and Medicare, and the amount of uncompensated care provided by the entity;~~

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- ~~(e) Utilization data, including types of procedures;~~
- ~~(d) Operating policies, including hours of operation;~~
- ~~(e) Patient specific or patient aggregate data, including demographic data, reimbursement source and levels, and patient disposition data; and~~
- ~~(f) Staffing requirements and patterns.~~

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.06 Access to Information and Facilities.

To the extent permitted by law, an applicant shall provide access to general information, records, plans and specifications, meetings, sites, and facilities to ~~the~~ Commission ~~staff~~ upon proper notice and as is reasonable and necessary in the performance of the Commission's responsibilities. The Commission may require other ~~providers of health care~~ ~~providers~~ to provide similar information. ~~to the extent permitted by law.~~

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07 Application Required for Certificate of Need Review- Preapplication Procedures

A. Application Form.

~~(1) A proposed new health care facility or health maintenance organization, or an existing health care facility or health maintenance organization planning a change covered by these regulations or by State law, shall submit a formal application for Certificate of Need, in the form and manner prescribed by the Executive Director. The nature and extent of information required may vary according to the type or scope, or both, of the proposed project or services.~~

~~(2) The Commission publishes separately from these regulations the application forms to be used for various categories of projects, and these application forms may be revised periodically. However, an application is not complete unless the applicant has provided to the Commission all surveys required of the applicant by the Commission through regulation.~~

~~(3) An applicant may petition the Commission, showing good cause why a survey required by the Commission through regulation has not been provided. The Commission shall docket the application as complete if it determines that good cause has been shown and the application is otherwise complete.~~

~~B. Submission to the Commission. A formal application for a Certificate of Need, or any information provided by an applicant in support of an application in accordance with Regulations .08—.10 of this chapter, shall be submitted to the Commission's Health Facilities Coordination Office.~~

C. Letter of Intent.

~~(1) A prospective applicant for a Certificate of Need shall submit to the Center for Health Care Facilities Coordination Office Planning and Development a brief letter of intent, with a copy to each local health department in the health planning region. The Center for Health Care Facilities Coordination Office Planning and Development shall formally log all letters of intent upon receipt.~~

~~(2) The letter of intent shall include the following information:~~

~~(a) The identity of each person on whose behalf the letter of intent is filed, including:~~

~~(i) The name and address of each such person; and~~

~~(ii) In the case of a letter of intent filed on behalf of a person that is not a natural person, the date the entity was formed, the business address of the entity, and the identity and percentage of ownership of all persons having an ownership interest of 5 percent or more in the entity;~~

~~(b) A description of the proposed project;~~

~~(c) The quantity and types of beds or health services involved; and~~

~~(d) The specific location and each jurisdiction in which services will be provided, according to the relevant planning region in the State Health Plan for that facility or service.~~

~~(3) Letters A letter of intent are valid for 180 days. If, at shall be submitted in accordance with the end published review schedule established by the Commission in accordance with~~

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~~§D(1) of 180 days from receipt of this regulation, but if no applicable review schedule has been published, a letter of intent by the Health Facilities Coordination Office, an application for Certificate of Need has not been filed, the~~ may be submitted at any time.

~~(4) Notice of the receipt of a letter of intent is void for a project not subject to a published review schedule shall be placed in the Maryland Register, and a 30-day period initiated for the submission of any other letters of intent for the same service in the same planning region to be included in the same review.~~

~~(5) Upon docketing of an application, the letter of intent for that project is no longer valid for purposes of comparative review, as set out in Regulations .08—10 of this chapter.~~

~~(5) The letter of intent shall be received by the Health Facilities Coordination Office not less than 60 days before the submission for docketing of a Certificate of Need application for the project. An application submitted before either the scheduled date for the submission of applications under Regulation .08A of this chapter or 60 days from the receipt of the required letter of intent may, at the discretion of the Commission, be held in abeyance and not formally reviewed until the next applicable review period.~~

~~(6) A prospective applicant may request that the Executive Director waive the 60-day waiting period before an application may be submitted, as provided in §C(5) of this regulation.~~

~~(7) If a letter of intent is submitted for a proposed health care project which might be comparable to a project application which has been submitted but not yet docketed, the 60-day period may not be waived. If the project proposed in the letter of intent and the project proposed in the application are determined to be comparable by the Commission, the projects shall be given a comparative review.~~

~~(8) If an applicant requests that the 60-day period be waived, the applicant shall agree that if a subsequent letter of intent for a similar health care project is filed within the period of time between submission of the applicant's application and the end of the 60-day period described in §C(5) of this regulation, the docketing of the applicant's project shall be suspended, and the comparative review shall be triggered in accordance with Regulation .08A(2) of this chapter.~~

~~(7) If a person submits a letter of intent for a proposed health care project that might be comparable to an application which has already been docketed, the Commission may not grant a waiver of the 60-day period and a comparative review may not be conducted.~~

~~(8) If an application for a CON is not filed in accordance with Regulation .08A(1), the letter of intent is void.~~

~~(9) Letters of intent are subject to public inspection during normal business hours.~~

D. The Applicant. B.

~~(1) If a proposed facility would require licensure after Certificate of Need approval, the applicant is the person or persons who will be the licensee as specified in Health General Article, §19-318 et seq., Annotated Code of Maryland. A person may file a letter of intent and an application in the person's own name, and, before docketing, designate an alternate legal entity that the person owns or controls as the intended licensee.~~

~~(2) Health care facilities or health maintenance organizations participating in the health care project are identified as co-applicants.~~

~~(3) One or more persons shall be officially authorized to sign for and act for the applicant for the specific project.~~

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~~¶~~ B. Preapplication Conference. After the filing of a letter of intent ~~or as scheduled under Regulation .08A(2) of this chapter, the~~, an applicant may request that the Commission staff ~~shall~~ arrange ~~to meet with each person who filed a letter of intent~~ a preapplication conference, to discuss:

- (1) ~~(4)~~ Commission procedures for reviewing the application or applications;
- (2) ~~(2)~~ Information and data to be included in the application or applications;
- (3) ~~(3)~~ The State Health Plan requirements that may affect the project; and
- (4) ~~(4)~~ Other matters relevant to the filing and processing of the application or applications.

~~¶C~~. The discussions in §~~¶B~~ of this regulation are informal, and statements at the meetings are not admissible as evidence at a Commission proceeding.

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10.24.01.08 Procedure for Review of CON Applications.

A. Review Schedule.

(1) An application shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no applicable review schedule has been published ~~for a service~~, an application may be submitted ~~at any time 60 days after the filing of the letter of intent but no more than 180~~ days after the filing of the letter of intent, unless a shorter period has been approved by the Executive Director.

~~(2) An application for which a review is scheduled may only be reviewed according to that schedule.~~

~~(2) If the Commission has not published a schedule for Certificate of Need review for a specified service, and the current State Health Plan does not preclude new capacity for that service in the relevant planning region, a letter of intent may be submitted at any time for that service. Notice shall be placed in the Maryland Register, and a 30-day period initiated for the submission of any other letters of intent for the same service in the same planning region to be included in the same review.~~

~~(4) In a case when need for additional service capacity is projected, the Commission may~~shall not docket an application until it has made a final decision on each previously docketed application for a similar project.

B. Submission of Application.

(1) An application ~~for a CON~~ shall be submitted to the Commission's Center for Health Care Facilities Coordination Office in accordance with ~~the schedules set forth in §D(1) of this regulation~~ form and manner prescribed by the Commission.

(2) The application, and all information supplementing the application, shall be signed by at least one principal of the applicant, who shall sign a statement as follows: "I solemnly affirm under penalties of perjury that the contents of the application (or the supplementary information) are true to the best of my knowledge, information, and belief."

~~(3) At the time of filing an application for a Certificate of Need or a modified application, an applicant shall submit six copies of the application to the Commission, unless the Commission requests that additional copies be filed, and shall send one copy to each other applicant in the review, to the local health department in each affected jurisdiction, and to any other person designated by the Commission, and shall certify delivery of the copies in writing to the Commission within 5 working days of the filing of the application with the Commission.~~

C. Completeness Review and Docketing.

(1) ~~Within 10~~ Prior to docketing an application for review and within ten business days of the filing of an application, ~~the Commission~~ staff shall review the application for completeness ~~to determine whether an application may be docketed for review.~~

(2) ~~The Commission~~ staff ~~shall~~ may schedule ~~with the applicant an application review a~~ conference with the applicant within the ~~40~~ ten-day period for completeness review.

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(3) ~~The Commission~~ staff shall determine whether the application contains all the information required. ~~Staff's requests for additional information to ensure~~ requested in the application. If staff determine that the application is not complete ~~shall specify in writing, the staff shall make a written request for additional information that specifies the information requested, which shall be submitted within 10 business days, and the 10-day deadline for the applicant to supply the requested information.~~ Additional information may be requested by staff beyond that required to make the application complete, which shall also be subject to a time limit for the applicant to supply the requested information.

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(4) If ~~the staff's~~ Commission staff determines, based on staff's review of the application ~~determines and any additional information provided in response to a staff request for additional information,~~ that the application is complete and conforms with the applicable docketing rules in the State Health Plan, ~~the~~ staff shall docket the application for review ~~as and publish notice of the docketing on~~ the next available publication date of the *Maryland Register*.

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(5) If an applicant fails to supply the required information within the specified time limit, staff may dismiss ~~and return~~ the application ~~and proceed with the review.~~ Staff may, at its discretion, extend the response time for an applicant in a noncomparative review, or, with the consent of all applicants, for an applicant in a comparative review, ~~for~~ up to an additional ~~10~~ten business days.

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(6) ~~The reviewer, staff, or the~~ Commission staff or a reviewer may:

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(a) Request information from the applicant supplementing an otherwise complete application at any time during the review of an application; and

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(b) Set reasonable time limits for the applicant to supply the requested information.

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D. Notice to the Public.

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(1) At least once each year, ~~the~~ Commission staff shall publish in the *Maryland Register* a schedule for conducting reviews of applications for designated services by health planning region, ~~as follows:~~

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~~(a) The schedule shall include the status of applicable need forecasts found in the State Health Plan or published elsewhere as required by the State Health Plan for conducting the reviews of the designated services by health planning region;~~

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~~(b) The schedule shall establish application submission dates not sooner than 3~~three months following the publication of the proposed schedule, ~~and 2~~

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~~(c) The schedule shall identify scheduled reviews by health planning region and shall state the dates for the receipt of letters of intent, and for the simultaneous submission of applications.~~

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(2) ~~Within 10 business days, the~~ Commission ~~staff~~ shall request that the *Maryland Register* publish notice ~~to the public~~ of the ~~receipt~~docketing of an application ~~and, when the application is complete, its docketing~~. The Commission shall also publish notice in a newspaper of general circulation in the area of the proposed project. ~~This notice~~ Notices shall comply with the State Government Article §10-207, Annotated Code of Maryland, and shall include:

(a) A citation to the Commission's enabling act and these regulations, the name of the applicant, the matter or docket number, and a general description of the project containing the information required in letters of intent;

(b) An explanation that a person who meets the definition of "interested party" in Regulation .01B of this chapter may become an interested party to the review of this application by submitting written comments on the application within 30 days of its docketing; and

(c) A statement that a person may request in writing that the Commission advise them of further notices of the proceedings on the application, and that any further notice of proceedings will only be sent to persons who have submitted a written request.

(3) If an evidentiary hearing is held in accordance with Regulation .10D of this chapter, the Commission shall provide notice to each person who has requested to be apprised of further proceedings on the application. ~~The notice shall include a:~~

- (a) ~~Reference to the authority under which the hearing is to be held and the rules of procedure for the holding of an evidentiary hearing; and~~
(b) ~~Statement that any person may attend the hearing.~~

E. Modifications to Letters of Intent and Applications.

(1) An applicant shall give written notice to the ~~Center for Health Care Facilities~~ Coordination Office ~~Planning and Development~~ of any modifications to the applicant's letter of intent before submitting an application.

(2) An application may be modified until the 45th day after docketing ~~or~~. After the 45th day of docketing, an application may only be modified as a result of a project status conference held pursuant to Regulation .09A(2) of this chapter. ~~After the 45th day, or upon a modification to an application in a comparative review not made as the result of a project status conference requires the consent showing of each applicant. In a noncomparative review, modifications to an application to reduce capital or operating costs, reduce annual projected revenue, reduce the level or number of beds and services requested, or to respond to relevant changes in the State Health Plan review criteria, policies, or need projections, are permitted at any time, good cause.~~

(3) If an application is modified:

(a) The Commission shall provide:

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(i) Notice of the changes by a dated posting on the Commission's website and in a newspaper of general circulation in the affected jurisdiction; and

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(ii) A ~~40-ten~~ business day period following the website posting for comments on the changes; and

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(b) Each applicant in the review will be deemed to have waived the right to a final decision by the Commission within the statutorily prescribed time.

~~(4) Changes to those portions of an application referring to facilities and services that are not subject to Certificate of Need review are not considered a modification to an application.~~

~~(5)~~
(4) The following modifications to a proposed project require a new Certificate of Need application:

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(a) Changes in the fundamental nature of a proposed facility or the medical services to be provided; ~~or~~

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(b) Increases in the total ~~licensed~~ bed capacity of a proposed facility; or

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~~(c) beyond that permitted by Health-General Article §19-307.2, Annotated Code of Maryland, or medical service categories. A change in the site of a proposed facility.~~

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F. Comments by a Person Seeking Interested Party Status or by a Participating Entity and Applicant's Response.

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(1) Written Comments by a Person Seeking Interested Party Status.

(a) A person seeking interested party status shall file written comments on an application within 30 days of docketing.

(b) The comments shall include information ~~that the~~ sufficient to establish interested party ~~wishes the Commission to consider~~ status, as defined in reviewing an application-Regulation .01B of this chapter.

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(c) If a person seeking interested party status is opposing an application, the comments shall state with particularity the State Health Plan standards or the review criteria in §G of this regulation that the person seeking interested party status believes have not been met by the applicant and the reasons why the applicant does not meet those standards or criteria.

(d) Factual assertions made in comments by a person seeking interested party status that are not included in the record shall be accompanied by appropriate documentation ~~or and~~ sworn affidavit ~~or both.~~

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(e) In a review with only one applicant, the comments shall be 25 pages or fewer, double-spaced, excluding attachments.

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(f) In a comparative review, the comments shall be 35 pages or fewer, double-spaced, excluding attachments.

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(2) Written Comments by a Person Seeking Participating Entity Status.

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(a) A person seeking participating entity status shall file written comments on an application within 30 days of docketing that:

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(i) Include information that the participating entity wishes the Commission to consider; and

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(ii) State with particularity the State Health Plan standards or review criteria in §G of this regulation that it believes have not been met by the applicant, and the reasons why the applicant does not meet those standards or criteria.

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(b) A person granted participating entity status shall be copied on Commission documents in the review of the application.

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(c) A person granted participating entity status ~~shall have its comments on~~ is not an applicant's conformance with State Health Plan standards interested party and has no right to judicial review criteria considered and analyzed by Of a reviewer in a proposed decision or by final Commission staff in a staff report to an application- decision.

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(3) Response to Comments.

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(a) An applicant is permitted to make one written filing responding to all written comments on its application within 15 days of receipt of those comments.

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(b) The applicant's response may not be more than 25 pages, double-spaced, excluding attachments.

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(c) In a comparative review, the ~~comments~~ applicant's response may not be more than 35 pages, double-spaced, excluding attachments.

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(d) Factual assertions ~~that are made~~ in an applicant's response ~~and that~~ are not included in the record shall be accompanied by appropriate documentation ~~or~~ and sworn affidavit ~~of both.~~

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G. Criteria for Review of Application.

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(1) In ~~proceedings on a~~ Certificate of Need ~~application review, the applicant carries the~~ burden of ~~proof~~ proving by a preponderance of the evidence that the project meets the applicable criteria for review, ~~by a preponderance of the evidence, rests with the applicant.~~

(2) ~~Issuance of a Certificate of Need by the Commission.~~ In reviewing an application for a ~~Certificate of Need~~ CON, the Commission shall consider the applicant's submissions, the ~~responses of each other applicant and interested party, the recommendation~~ comments, if any, of ~~the interested parties, participating entities, the local health department, and the information gathered during the Commission's~~ Commission's review of the application, to which each applicant and interested party ~~shall have~~ has been afforded ~~an~~ the opportunity to respond. In a comparative review the Commission shall award a CON to the applicant, or applicants, that best meet the review criteria in §G(3) of this regulation.

(3) Criteria for Review of an Application for Certificate of Need.

(a) State Health Plan. An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, ~~policies, and criteria.~~

(b) Need. The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated ~~unmet needs of the population to be served, and established that~~ a need for the proposed project ~~meets those needs.~~

~~(c)~~ (e) Availability of More Cost Effective Alternatives. ~~The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.~~

Alternatives to the Project. The Commission shall consider the alternative approaches to meeting the need identified for the project that were considered by the applicant in planning the project and the basis for the applicant's choice of the project among considered alternatives. In a comparative review of applications within the same review cycle, the Commission shall compare the costs and the likely effectiveness of alternative projects in meeting identified needs, improving the availability and accessibility of care, and improving the quality of care.

(d) Project Financial Feasibility and Facility or Program Viability ~~of the Proposal.~~ The Commission shall consider the availability of ~~financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of~~ resources necessary to sustain the project, implement the project and the availability of revenue sources and demand for the proposed services adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced.

(e) Compliance with Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous ~~Certificate of Need~~ CON granted to the applicant, ~~and with all commitments made that earned preferences in~~

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~~obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.~~

(f) Project Impact on Existing Providers and the Health Care Delivery System. An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system; the costs and charges for the facilities and services included in the project and on access to those facilities and services in the service area of the project.

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.09 Commission Decision and Action on CON Applications.

A. Proposed Decision.

(1) Preparation of Proposed Decision.

(a) In a noncomparative review in which no interested party has submitted written comments opposing an application, or in a review in which no evidentiary hearing is held in accordance with Regulation ~~.10D11~~ of this chapter, the Commission staff shall review the application and prepare a staff report and recommendation for consideration by the full Commission.

(b) In all other reviews, the Executive Director shall appoint a single Commissioner, who may be assisted by the staff of the Commission, to act as reviewer and prepare a proposed decision for consideration by the full Commission.

(2) Project Status Conference.

(a) The reviewer or staff, as appropriate, may request that a project status conference be held before the issuance of a proposed decision or staff report, to apprise each applicant, interested party, and participating entity of those aspects of a proposed project that appear to be inconsistent with applicable standards and review criteria.

(b) Following the project status conference, the reviewer or staff will send each applicant, interested party, and participating entity a summary of the project status conference that includes dates, as needed, for additional filings.

(c) The applicant shall send to each interested party and participating entity a copy of proposed project changes made pursuant to the project status conference.

(d) Each interested party and participating entity in the review of an application shall have ~~seven~~ days to file comments on the proposed changes made pursuant to the project status conference.

(3) Opportunity to Present Oral Argument. Each applicant and interested party in a contested or comparative review may request the opportunity to present oral argument to the reviewer before the reviewer prepares a proposed decision on the application for consideration by the full Commission, as follows:

(a) The request shall be made within the time period for an applicant's response to comments under Regulation .08F(~~23~~) of this chapter;

(b) The decision to grant oral argument is at the sole discretion of the reviewer;

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(c) The reviewer may set reasonable time limits for oral argument; and

(d) The reviewer may, if there is a genuine dispute as to the credibility of a material witness on a matter of fact, require the witness to answer questions on that matter under oath during the oral argument portion of a ~~Certificate of Need~~ CON review.

(4) ~~The~~ A staff report and recommendation on a proposed project or a reviewer's proposed decision on a project shall state the staff's conclusion or the reviewer's determination ~~finding~~ as to whether:

(a) Each relevant State Health Plan standard or review criterion set forth in Regulation .08G of this chapter:

(i) Is met by the applicant,

(ii) Is not applicable to the project, or

(iii) Is applicable to the project and is not met by the applicant;

(b) In a comparative review, one or more of the projects ~~should be~~is preferred under a State Health Plan standard or ~~criteria~~critereion either as a result of ~~meeting~~consideration of a preference standard or because ~~an applicant complied with one or more criteria in a~~of the projects ~~was determined to be superior way relative to another applicant based on the reviewer's~~ consideration of the applicable criteria; and

(c) To recommend that ~~a project~~one or more of the projects be granted a ~~Certificate of~~
Need. CON.

B. Exceptions.

(1) ~~Each~~Pursuant to State Government Article §10-216, Annotated Code of Maryland, ~~each~~ applicant and interested party who has submitted ~~written~~ comments under Regulation .08F(1) of this chapter may submit written exceptions to a staff report and recommendation or a proposed decision and ~~order by submitting written~~ make oral argument and supporting documentation from the record to the Commission.

(2) ~~Schedule.~~

(a) Upon issuance of a staff report or proposed decision, Commission staff shall issue a notice specifying the schedule for the submission of exceptions and any response, ~~and~~ the date on which the Commission shall hear oral argument ~~on~~, and rules for conduct of the ~~exceptions~~ hearing.

(b) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff shall specify that exceptions shall be filed at least 15 days before the Commission meeting at which the proposed decision and order will be considered, and any response to the exceptions filed at least 10 days before the Commission meeting.

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~~meeting, except that a party filing exceptions has at least 7 days to file exceptions, and a party filing a response to exceptions has at least 5 days to file a response. The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.~~

(3) ~~Written exceptions~~ Exceptions shall specifically identify each finding and conclusion to which exception is taken, citing those portions of the record on which each exception is based.

- (a) Exceptions shall be limited to 25 pages, double-spaced, excluding attachments.
(b) Responses to exceptions shall be limited to 15 pages, double-spaced, excluding attachments.

(4) Oral arguments before the full Commission concerning the proposed decision are limited to ~~10ten~~ minutes per applicant and ~~10ten~~ minutes per interested party, unless extended by the ~~Chairman~~ Chair of the Commission. An applicant may reserve time for rebuttal.

C. Participation By Participating Entity In Certain Reviews After Issuance of a Staff Report or Reviewer's Proposed Decision.

(1) Request by Participating Entity ~~Request~~ to Address the Commission.

(a) ~~In a project upon which it timely filed comments on an applicant's conformance with State Health Plan standards and review criteria, and after~~ After the issuance of a staff report or a reviewer's proposed decision, ~~and at least 3 days before the scheduled Commission meeting that will consider an application, a~~ participating entity may ~~notify~~ request the Commission that it desires opportunity to address the Commission before Commission action on the application. by submitting a written request at least three days before the scheduled Commission meeting that will consider an application, specifying the points that it wants to make.

(b) The ~~Chairman~~ Chair of the Commission, after consultation with the ~~executive director~~ Executive Director, may permit a participating entity, or combination of participating entities, to make an oral presentation to the Commission on matters it addressed in written comments on the application.

(c) At least ~~one~~ one day before the scheduled Commission meeting that will consider an application, the ~~executive director~~ Executive Director shall advise each applicant, interested party, and participating entity in a review whether the ~~Chairman~~ Chair will permit a participating entity or combination of participating entities to make an oral presentation to the Commission, and shall specify the format of the presentation.

(2) An applicant may address the Commission in any review in which a participating entity is granted permission to address the Commission before action on an application.

(3) ~~This section does not:~~

- (a) ~~Confer interested party status or aggrieved party status upon a participating entity; or~~

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~~(b) Grant a participating entity the right to judicial appeal under State Government Article, Title 10, Annotated Code of Maryland.~~

D. Final Decision.

~~(1) The Commission shall issue a Commission's final decision based on the record of the proceeding. The final decision shall take one of the following two forms:~~

~~(a) A statement of exceptions that have been accepted, if any, a project shall contain findings of fact and a statement that the proposed decision is adopted into the final decision except as otherwise noted; or conclusions of law and;~~

~~(b) A new final decision in the format for proposed decisions, as specified in §A(3) of this regulation.~~
~~(2) The Commission's decision shall do one of the following:~~

~~(a) Approve the application;~~

~~(b) Approve the application with conditions; or~~

~~(c) Deny the application.~~

~~(2) The decision of the Commission shall be by a majority of the quorum present and voting.~~

E. Action on the Application.

~~(1) The Commission shall act on an application for a Certificate of Need CON, not later than 150 days after the application has been docketed. If no evidentiary hearing is held, the Commission shall act on an application within 90 days after the docketing of the application. Staff shall report to the Commission the status of all projects where a staff report is not issued for Commission action within 90 days.~~

~~(2) With the exception of CON applications to establish a health care facility, relocate a health care facility, or establish cardiac surgery services or organ transplantation services at an existing acute general hospital, a CON application filed after October 1, 2019, shall be deemed approved if the application is uncontested and final action by the Commission does not occur within 120 days after the application is docketed.~~

~~(3) A review of a CON application may be stayed for a period not to exceed six months if the reviewer, or if a reviewer is not appointed, the Executive Director, determines that there is good cause for a stay.~~

~~(4) The Commission shall notify the applicant, interested parties, participating entities, and the local health department, of one of the following determinations: Commission's final decision.~~

~~(a) The project is granted a Certificate of Need;~~
~~(b) The project is granted a Certificate of Need with specific conditions; or~~
~~(c) The project is not granted a Certificate of Need.~~
~~(3) The decision of the Commission shall include findings of fact and conclusions of law.~~

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- ~~(4) The decision of the Commission shall be by a majority of the quorum present and voting.~~
(5) The decision shall be in writing and shall state the reasons and grounds for the Commission's decision.
~~(6) The Commission may not render a final decision until:~~
(a) A
(a) A staff report and recommendation or a reviewer's proposed decision, including findings of fact and conclusions of law, has been served upon provided to each party; and
(b) Each party adversely affected by the proposed decision applicant and interested party has been given an opportunity to file exceptions and present oral argument before the Commission.

F. Judicial Review.

- (1) The Commission's final decision is subject to the judicial review under State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.
- (2) In order to take a seek judicial appeal, an interested review, a party must be an aggrieved party.
- (3) For purposes of judicial review, the record of the proceeding shall include:
- (a) The application;
- (b) Requests to an applicant for additional information from Commission staff, the reviewer, the Commission, or Commission staff, and responses to them; the requests;
- (c) Comments received from each interested party, and supporting documentation, affidavits, and responses from each applicant;
- (d) Reports or recommendations from staff;
- (e) Motions and pleadings; responsive filings;
- (f) The prehearing conference report, if any;
- (g) Prefiled testimony, if any;
- (h) A recording or transcript of any hearing;
- (i) The reviewer's proposed decision, and all exceptions, and responses to exceptions; and

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▲(j) The Commission's final decision.

▲(4) A decision of the Commission is a final decision for purposes of judicial review.

▲(5) A request for reconsideration in accordance with Regulation .19 of this chapter will stay the final decision of the Commission for purposes of judicial review until a decision is made on the Commission decides the request for reconsideration. ▲

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10 Miscellaneous Rules and Procedures.

A. Filing Computation of Documents with the Commission. Time

(1) In computing a period of time prescribed by these regulations, by order of the Commission, or by an applicable statute, the day of the action or default initiating the designated period of time is not included. The last day of the period so computed is to be included unless it is a day on which the office of the Commission is closed, in which event the period extends until the next day on which the office of the Commission is open. Unless otherwise noted, all time periods shall be computed in calendar days.

(2) At the discretion of the reviewer, the Executive Director, or the Executive Director's designee, and upon a showing of ~~substantial reasons~~ good cause by the submitting party, a period of time to submit a document or perform any act permitted or prescribed by these regulations may be extended for a reasonable period of time.

⁽³⁾
B. Filing of Documents. In all matters before the full Commission, filings may not be made directly to individual commissioners except at the direction of the reviewer, ~~the Executive Director,~~ or the Executive ~~Director's designee~~ Director.

C. Motion Practice.

(1) A motion shall be made in writing, except when made at a hearing or prehearing conference in accordance with Regulation .11 of this chapter, and shall state concisely the ~~question which the Commission is called upon to determine, or the~~ action the movant desires the Commission to take. ~~It shall state all reasons, authorities, and citations in the body of the motion or in a supporting memorandum-grounds and authority.~~

(2) A motion ~~made in response to a determination by the Commission or its staff~~ shall be filed within 20 days of the determination to which the motion responds.

(3) The following actions shall be taken by motion:

(a) A demand for an action which the movant desires the Commission, the reviewer, or the staff of the Commission to take;

(b) A request for reconsideration, under Regulation .19 of this chapter;

(c) An objection to the introduction of a statement or other evidence by a party during an evidentiary hearing held under Regulation .11 of this chapter;

(d) A challenge to a reviewer or other member of the Commission;

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(e) An action that might be initiated properly or undertaken by a party to a review, and that is not otherwise provided for in these regulations; and

(f) Any other question that is justiciable.

(4) A motion need not be verified unless it is based on facts not apparent from the record or documents filed in the proceeding.

(5) ~~A~~An applicant or interested party to the ~~hearing~~review, may file one written answer to a motion, in the same format required of motions, within five days of the filing of the motion.

(6) Except as otherwise provided in these regulations, the reviewer or, in a matter in which no reviewer has been appointed, the Executive Director shall rule on a motion made prior to the issuance of a proposed decision or staff recommendation. Except as otherwise provided in these regulations, the Chair shall rule on all other motions.

(7) The person presiding over the motion may hear oral argument on the motion at the request of a party.

D. Summary Decision.

(1) At any time after an application is docketed, staff may file ~~a~~ motion for summary decision to deny the application.

(2) The motion shall identify the grounds for the motion, which is not required to address every applicable State Health Plan standard. The applicant may respond to the motion in writing, within ten days of receipt of the motion.

(3) The reviewer, or, in a matter in which no reviewer has been appointed, a commissioner appointed as motions officer by the Executive Director, may hear oral argument on the motion at the request of a party and shall issue a proposed ruling which shall be subject to review by the full Commission.

C. Summary Decision.

(4) A quorum of the full Commission shall make

~~(1) At any time after an application is docketed, staff may file a~~ final ruling on the motion for summary decision.

~~E. to deny~~ Ex Parte Contacts. After the docketing of an application and until the Commission renders its final decision under this regulation, the ex parte provisions of the Administrative Procedure Act, State Government Article, Title 10, Annotated Code of Maryland, apply.

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F. Local Health Department Review and Comment. The Commission shall seek information and comment from each local health department in the health planning region for the proposed project, and shall consider any response from each health department in making a ~~deeketed~~ final decision on an application.

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G. Required Approvals.

(1) if the proposed project is inconsistent Except in emergency circumstances posing a threat to public health, all decisions of the Commission on an application for a certificate of need, shall be consistent with ~~one or more standards of the applicable~~ State Health Plan ~~that make the project unapprovable.~~ standards and criteria established by the Commission.

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(2) Unless the Commission finds that the facility or service for which a proposed expenditure is to be made is not needed or is not consistent with the State Health Plan, the Commission shall approve an application for a certificate of need to the extent that the expenditure will be made to eliminate or prevent an imminent safety hazard, as defined by federal, State, or local fire, building, or life safety codes or regulations, to comply with State licensing standards, or to comply with accreditation standards for reimbursement under Title XVIII of the Social Security Act or under the State Medical Assistance Program approved under Title XIX of the Social Security Act.

H. Notice of Final Action on a Certificate of Need Application. The Commission shall provide a copy of a CON decision to State or local licensing agencies, the Maryland Medical Assistance Program, and the Health Services Cost Review Commission.

I. Participation of Staff. A reviewer may seek the assistance of any member of the Commission staff in preparing a proposed decision.

J. Transferability. A Certificate of Need or other Commission approval is not transferable.

K. Consent Agenda.

(1) The Commission may take action on the following categories of items by use of a consent agenda at a public meeting of the Commission:

(a) Adoption of final regulations previously adopted by the Commission as proposed permanent regulations that:

(i) Do not result in public comments after publication in the Maryland Register;
and

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(ii) Contain no wording changes.

(b) A change in an approved project that requires Commission approval pursuant to Regulation .17 and is recommended for approval by the Executive Director with the exception of:

(i) An increase in the capital cost of a project that exceeds the approved capital cost inflated by the cost index specified in Regulation .17 that also includes a change in the financing mechanism of the project; or

(ii) A change in the financing mechanism of the project.

(c) Other categories of actions that a majority of the fully authorized membership of the Commission votes to include on the consent docket.

(2) An item on the consent agenda shall be moved to the main agenda of the upcoming meeting or the meeting that follows if a Commissioner requests that the item be moved to the main agenda.

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11 Evidentiary Hearings.

(2) The motion shall identify the grounds for the motion and the staff's position and argument. The motion need not address every State Health Plan standard. The affected applicant has the opportunity to respond to the motion in writing.

(3) If staff is reviewing the application, as specified in Regulation .09A(1)(b) of this chapter, a quorum of the full Commission shall decide the motion.

A. Request for

~~(4) If a commissioner is acting as reviewer, that commissioner shall decide the motion, subject to review by the full Commission. An affected applicant has 10 days to respond to the motion in writing and, at the applicant's request, to present oral argument to the reviewer before the reviewer rules on the motion.~~

D. Evidentiary Hearing.

~~(+)~~

(1) Except as otherwise provided in these regulations, a request for an evidentiary hearing shall be made within 45 days of the docketing of an application or within 30 days after the modification of an application in a review.

(2) At the request of an applicant or interested party in a Certificate of Need, the Commission may hold an evidentiary hearing in the review; an evidentiary hearing may be held on any Certificate of Need a CON application for the construction of an acute general or special hospital.

(2) An evidentiary hearing may not be held on an application for any health care facility other than an ambulatory surgical facility or new or expanded ambulatory surgical capacity in a setting owned or controlled by a hospital.

(3) If an applicant requests a hearing to show cause why a Certificate of Need should not be withdrawn, the Commission shall hold an evidentiary hearing before it withdraws a Certificate of Need, under Regulation .12 of this chapter.

~~(4) The Commission may hold an evidentiary hearing in a Certificate of Need review for a proposed new facility or service if, in the judgment of the reviewer, an evidentiary hearing is appropriate due to the magnitude of the impact that the proposed project would may have on the existing health care delivery system, by meeting the requirements of this subsection and of §D(5) of this regulation. The and the project, if approved, would result in one of the following:~~

(a) A significant increase in public costs, or in substantial negative impact on the costs and charges paid by a substantial number for the type of patients the facility, services, or both included in the project;

(b) A substantial negative impact on access to those facilities and third-party payors; services by the population in the proposed project's expected service area;

(c) A significant decrease in the availability and overall quality of health care services in the affected area in a manner not consistent with policies or need projections set forth in the State Health Plan, such as by causing a loss of reasonable access to an essential medical service by a substantial number of patients; or

(e) An additional demand on limited resources available to support health care facilities or medical services in a proposed service area that has existing budgetary and competitive constraints, such as a high penetration of managed care, or a high level of existing excess capacity; or

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(d) Any impact that the reviewer concludes may be sufficiently serious to merit an evidentiary hearing.

~~(5) An evidentiary hearing will assist the reviewer in resolving questions of material fact or witness credibility.~~

~~(6) Request for Evidentiary Hearing:~~

~~(a) Each applicant and interested party may request that the reviewer conduct an evidentiary hearing on a proposed project by the 45th day after docketing, or within 30 days of a modification of an application in a review.~~

~~(b) The reviewer may hear oral arguments from any party on the question of whether to conduct an evidentiary hearing.~~

~~(e) An interested party may appeal an adverse ruling on this question by motion to the full Commission at its next regular meeting.~~

~~(7) The evidentiary hearing shall be conducted in accordance with Regulation .11 of this chapter.~~

E. Ex Parte Contacts. After the docketing of an application and until the Commission renders its decision under this regulation, the ex parte provisions of the Administrative Procedure Act, State Government Article, Title 10, Annotated Code of Maryland, apply.

F. Local Health Department Review and Comment:

(1) The Commission shall seek information and comment from each local health department in the health planning region in which a proposed project may be located, and consider any response from the local health department in making a final decision on an application.

(2) The Commission shall consider a positive recommendation of the local health department to be one measure of community support for a proposed project. If a local health department makes a recommendation on a specific project, and the Commission's decision differs from that proposed by the local health department, the Commission shall make a written, detailed explanation as to the basis for the difference to the local health department.

G. Required Approvals. Unless the Commission finds that the facility or service for which the proposed expenditure is to be made is not needed or is not consistent with the State Health Plan, the Commission shall approve an application for a Certificate of Need to the extent that the capital expenditure is made to eliminate or prevent an imminent safety hazard, as defined by federal, State, or local fire, building, or life safety codes or regulations, to comply with State licensing standards, or to comply with the accreditation standards for reimbursement under Title XVII of the Social Security Act or under the State Medical Assistance Program approved under Title XIX of the Social Security Act.

H. Notice of Certificate of Need Approval:

(1) Notice that a facility or project has been granted a Certificate of Need shall be made in writing by the Commission to those agencies responsible under the licensure program and other agencies that may have interests or responsibilities related to the project.

(2) The notice shall be given at the same time that notice is given to each applicant, interested party, and the local health department.

(3) The notice of Certificate of Need approval shall contain the following information:

~~(a) The nature and scope of the approved health service or facility, described in suitable detail;~~

~~(b) The actual capital costs associated with the approved project, to include construction, equipment acquisition (whether by purchase or lease), architects' and consultants' fees, and all other costs, other than financing costs, to be incurred by the applicant in order to complete the project;~~

~~(c) The total principal amount of funds to be borrowed, if any, and a description of the terms of the financing mechanism through which this borrowing will be accomplished; and~~

~~(d) Each condition associated with the project approval.~~

I. Changes to an Approved Project. If an applicant proposes to make changes to an approved project, the applicant shall notify the Commission of the proposed change in accordance with the procedure established in Regulation .17 of this chapter.

J. Participation of Staff. The reviewer may seek the assistance of any member of the Commission staff in preparing a proposed decision.

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~~11 Evidentiary Hearings~~

~~A~~

~~B. General.~~

~~(1) (1) Informal Proceedings. At the request of an applicant, and if each interested party waives the right to present evidence, argument, and conduct cross examination, the reviewer may establish at the prehearing conference~~

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~~informal rules for mediation, structured negotiation, or another consensual procedure for reaching a decision. The procedure shall produce a record upon which the proposed decision can be based.~~

~~(2) Reviewer as Presiding Officer.~~

~~(a) If an evidentiary hearing is held in accordance with Regulation 10D of this chapter, the reviewer shall preside at the hearing.~~

~~(i) Conduct a full, fair, and impartial hearing;~~

~~(ii) Take action to avoid unnecessary delay in the disposition of the proceedings;~~

~~and~~

~~(iii) Maintain order.~~

~~(b) The reviewer is empowered to: has the power,~~

~~(i) Make all rulings as to evidence, testimony, official administrative notice, and the conduct of the regulate the course of an evidentiary hearing;~~

~~(ii) Set the date, time, and place the conduct of each hearing and prehearing the parties and deadline for any submission, and the order for the examination and cross-examination of witnesses; authorized representatives, including the power to;~~

~~(iii)~~

~~(i) Administer oaths and affirmations;~~

~~(ii) Rule upon offers of proof and receive relevant and material evidence;~~

~~(iii) (iv) Prepare oral and written summaries;~~

~~Consider and rule upon motions in accordance with this chapter;~~

~~(iv) Examine witnesses and call witnesses as necessary to ensure a full and complete record;~~

~~(v) Prepare Limit unduly repetitious testimony and reasonably limit the time for presentations;~~

~~(vi) Grant a continuance or postponement;~~

~~(vii) Modify or waive, reasonably and for good cause, any time periods established by this chapter;~~

~~(viii) Request that parties submit legal memoranda, proposed decision with findings of fact, and proposed conclusions of law; and~~

~~(vi) Take~~

~~(ix) Make proposed decisions and take any other actions consistent with appropriate action authorized by law;~~

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(x) Issue orders as are necessary to secure procedural simplicity and administrative fairness and to eliminate unjustifiable expense and delay;

(xi) Conduct the commissioner's duties as reviewer, hearing in a manner suited to ascertain the facts and safeguard the rights of the parties to the hearing; and

(c) The reviewer may ~~be assisted by one or more staff members and one or more assistant attorneys general assigned to the Commission. impose appropriate sanctions for failure to abide by~~

~~(d) The reviewer may delegate to one or more individuals specified in §A(2)(c) of this regulation the responsibility for consideration~~
chapter or any lawful order of a motion for extension of time. the reviewer.

(2) Conduct of Evidentiary Hearings.

(a) An evidentiary hearing need not be conducted according to technical rules of evidence, but shall be conducted in accordance with the Maryland Administrative Procedure Act, State Government Article, Title 10, Annotated Code of Maryland, and these regulations.

(b) Reliable hearsay is admissible.

(c) Rules of privileges are effective to the extent they would be effective in a judicial proceeding in Maryland.

(d) Nonexpert opinion testimony may be considered.

(e) Qualification as an expert lies within the discretion of the reviewer. The qualification of an expert need not be based on academic degrees ~~or learning~~. Reasonably extensive practical experience with the subject may be sufficient for an expert qualification.

(f) Reliable and probative documents previously filed with or compiled by the Commission or its staff or consultants that are relevant to issues being considered by the Commission may be incorporated by reference into the record of a proceeding by the Commission or, by leave of the reviewer, by a party to the proceeding, upon notice to the parties and an opportunity to object.

(g) The reviewer may take administrative notice of all judicially cognizable facts to the same extent as courts of this State, either on the reviewer's own motion or at the request of a party. The reviewer may also take official notice, without meeting formal evidentiary rules, of general technical or scientific facts within the specialized knowledge of a member of the Commission. ~~A party to the hearing is entitled, on timely request, to an opportunity to show that the Commission should not take administrative or official notice of specific facts and matters, or that the fact or matter to be officially noticed is inapplicable to the proceeding or is incorrect or misunderstood by the Commission.~~

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⁴
(3) A party to the hearing may be represented by counsel.

⁵
(4) The prehearing conference and the hearing shall be recorded. If an applicant or other person desires a transcript, that person shall ~~make arrangements with the stenographer~~ pay all costs to transcribe the recording.

⁶
(5) Documents filed in the proceeding shall be served on the reviewer, those specified in §A(2)(c) of this regulation, ~~staff~~, and each interested party, and shall include a certificate of service.

~~(7) Motion practice is in accordance with Regulation 10B of this chapter.~~

~~B.~~

C. Prehearing Procedures.

¹
(1) The reviewer ~~shall may~~ hold ~~at least one~~ prehearing conference, as well as settlement conferences, before an evidentiary hearing.

²
(2) The reviewer shall notify each applicant and interested party of the prehearing conference in writing. The notification shall:

(a) Include the date, time, and place of the prehearing conference or conferences;

(b) Summarize the rules of procedure governing the evidentiary hearing; and

²
~~(c)~~ State the dates, if known, for the submission of prefiled testimony and the date, time, and place of the evidentiary hearing.

(3) The principal purpose of the prehearing conference is to expedite the evidentiary hearing. To this end the reviewer may, among other things:

(a) Instruct the parties to:

~~(i)~~ Formulate and submit a list of genuine contested issues to be decided at the hearing;

~~(ii)~~ Identify each potential witness, the subject matter of each witness's testimony, and documents to be introduced; and

~~(iii)~~ Raise and address issues that can be decided before the hearing;

(b) Encourage stipulations as to facts, law, and other matters;

(c) Schedule dates for the submission of prefiled testimony, further prehearings, the hearing, and submission of briefs and documents; and

(d) Rule on any pending motions;

~~(4)~~ A written summary of the prehearing conference shall be made a part of the record of the proceeding.

(5) The reviewer may record the prehearing conference or have a stenographer present.

⁶
(6) A request for the postponement of a hearing shall be made at a reasonable time before the hearing and is granted only for good cause shown, at the discretion of the reviewer.

~~C.~~

D. List of Genuine Issues.

¹
(1) The reviewer shall ~~set the~~ establish a list of genuine issues of material fact for the evidentiary hearing.

²
(2) An evidentiary hearing may be held only on those genuine factual issues for which:

(a) There is a significant dispute as to factual ~~OR~~ issues; and

(b) One of on which the following is true:

¹
~~(i)~~ The reviewer designates a genuine issue;

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~~(ii) An applicant or an interested party has made a prima facie case that a particular standard or criteria has not been met by an applicant;~~

~~(iii) An applicant has made a prima facie case that it deserves preference over another applicant under that standard or criteria; or~~

(iv) The reviewer determines that testimony on an issue would be helpful.

~~D. Direct~~ useful in rendering a decision.

E. Written Direct Testimony.

(1) Direct testimony shall be in writing and may not be delivered orally.

(2) A party who wishes to present testimony at the evidentiary hearing shall file written testimony before the hearing in accordance with the schedule set by the Commissioner acting as reviewer.

(3) The written direct testimony shall set forth the conclusions of the person submitting it and all arguments and facts supporting these conclusions.

(4) Written direct testimony shall be verified either under oath at the hearing or by including the statement specified in Regulation .08B(2) of this chapter.

~~(5) Written direct testimony shall pertain solely to the proposed project and be relevant to that project.~~

(5) Upon notice with an opportunity to object, the reviewer shall separate irrelevant material from the remainder of the record and keep that material apart. Parts of the body of the written direct testimony judged irrelevant by the reviewer shall be so marked and may not be considered by the Commission in its deliberations.

(6) Persons submitting written testimony shall make themselves available for oral cross-examination. Submitted application materials are also subject to cross-examination. Letters submitted into the record which are not considered written testimony are not subject to cross-examination.

~~E.~~ F. Cross-Examination.

(1) Cross-examination of each witness shall be live and under oath.

~~(1) Cross-examination of each witness shall be live and under oath.~~

(2) The reviewer and each ~~nonproponent~~ non-proponent applicant and interested party may conduct reasonable cross-examination of a witness who gave direct or rebuttal testimony.

(3) The reviewer may set reasonable time limits on the cross examination of witnesses.

~~(2) The reviewer may set reasonable time limits on the cross examination of witnesses.~~

~~(4) The reviewer shall set a deadline by which each party shall identify any witness for whom that party does not have cross-examination.~~

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G.
~~F.~~ Rebuttal Testimony.

(1) ~~After direct testimony has been completed, rebuttal~~ Rebuttal testimony is permitted on any issue specified by the reviewer.

(2) Rebuttal testimony, whether specified by the reviewer to be written or oral, is subject to live cross-examination.

~~(2) Rebuttal testimony, whether specified by the reviewer to be written or oral, is subject to live cross-examination.~~

H. Post-Hearing Briefs.

~~(1) The reviewer may permit the filing of request post-hearing briefs by each.~~

I. Informal Proceedings. At the request of an applicant, and if each interested party, (2) The reviewer may set a filing deadline and page limit establish informal rules for mediation, structured negotiation, or another consensual procedure for post-hearing briefs, reaching a decision.

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12 Effective Duration Holder Responsibilities and Withdrawal of a Certificate of Need and Applicant Responsibilities or Other Commission Approval.

A. Project Implementation Schedule.

(1) A-Good Standing. The Certificate of Need issued CON or other application shall propose a schedule for implementation of the project by the that specifies the estimated time for, at a minimum, the following project implementation steps:

(a) The time required to enter a binding obligation following Commission approval of the application for the project;

(b) The time required to initiate construction, renovation, or both following execution of a binding obligation;

(c) The time required to complete the approved construction, renovation, or both following initiation of construction, renovation, or both.

(d) The time required to place the new facility or modified facility in operation following the completion of approved construction, renovation, or both.

(2) The proposed project implementation schedule for a project requiring a multiphased plan for implementation shall detail those multiple phases and specify the estimated time requirements for, at a minimum, the four time periods listed above for each phase.

(3) shall A holder must abide by the project implementation schedule submitted with its application for a CON or other Commission Approval.

(4) The project implementation schedule may be maintained in good standing reasonably modified by the applicant up to holder during the period during which the project is being implemented with approval of Commission staff.

B. Progress Report.

(1) Up until an approved project's completion, licensure, if required, and first use of the approved project, a holder shall submit a semiannual progress report in the form and manner prescribed by Commission staff.

B. The Certificate of Need shall be issued with specific performance requirements, as follows:

(1) There

(2) The semiannual progress report shall detail the holder's compliance with the project implementation schedule and any conditions on approval imposed by the Commission.

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(3) A holder shall submit the semiannual progress reports in accordance with the following schedule:

(a) The first report will be due at least 45 days before the six-month anniversary of the final action awarding the CON or other Commission approval;

(b) Subsequent progress reports shall be ~~an obligation of not less than~~ due every six months after the due date of the prior report.

C. Obligation.

(1) Except as provided by §C(2) of this regulation, a holder must obligate at least 51 percent of the approved capital expenditure for a project involving building construction, renovation, or both, as documented by a binding construction contract or equipment purchase order, within the following specified time periods:

(2) In the case of construction projects, the initiation of construction shall take place within 4 months of the effective date of a binding construction contract, and construction shall be continuous after that, subject to the following exception:

(a) If the approved project ceases continuous construction for a period in excess of 30 calendar days, the applicant shall notify the Commission in writing of the break in construction and submit for approval, documentation of the applicant's inability to control the break in construction within 35 calendar days of the work stoppage, and, within 45 calendar days of the work stoppage, submit to the Commission a plan of recommencement of construction not to exceed 90 calendar days, which period may be extended for a reasonable period if the applicant shows extraordinary circumstances; and

(b) The Commission shall consider any documentation submitted in determining whether good cause exists to grant a 6-month extension of the second performance requirement, in accordance with §E(1) of this regulation; and

(3) The applicant shall provide documentation that the approved project has been completed, has been licensed if required, or has otherwise met all applicable legal requirements and is providing the approved service or services within a specific time period beginning from the initiation of construction or from the effective date of a binding equipment purchase order.

C. Performance Requirements.

(1) Performance requirements shall be applied to approved projects with specific time limitations, beginning with the date of Certificate of Need approval, according to the nature and scope of the project.

(2) The requirements of §B(2) of this regulation apply to all approved construction projects.

(3) The requirements of §B(1) and (3) of this regulation apply, as follows:

(a) An approved new hospital has up to 36 months to ~~obligate 51 percent of the approved~~ capital expenditure, and up to 36 months after the effective date of a binding construction contract to complete the project; ~~document the required obligation;~~

(b) Major ~~(greater than \$5,000,000) additions, replacements, modernizations, relocations, or conversions to~~ an existing ~~A project involving an approved new non-hospital health care facility or~~ involving a building addition or replacement of building space of a health care facility has up to 24 months to ~~obligate 51 percent of~~ document the approved capital expenditure, and up to 24 months after the effective date of a binding construction contract to complete the project; ~~required obligation;~~

(c) ~~Except as provided in this subsection, a proposed new~~ A project limited to renovation of existing building space of a health care facility has up to 18 months to ~~obligate 51 percent of the approved capital expenditure, and up to 18 months after the effective date of a binding construction contract to~~ complete the project; ~~document the required obligation; and~~

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(d) ~~(d) A major change in bed capacity (greater than 40 beds or 25 percent of total licensed capacity); additions, replacements, modernization, relocation, or conversions to an existing inpatient health care facility that involves a capital expenditure between the threshold specified in Regulation .01B of this chapter and \$5,000,000 has up to 18 months to obligate 51 percent of the approved capital expenditure, and up to 12 months after the effective date of a binding construction contract to complete the project;~~

~~(e) A minor change in bed capacity, which falls below the limits described in §C(3)(d) of this regulation but which requires review under Regulation .02 of this chapter, has up to 12 months to obligate 51 percent of its approved capital expenditure, and up to 8 months after the effective date of a binding construction contract to complete the project.~~ A project that does not involve construction or renovation must document that the approved project is complete and operational within 18 months of project approval.

(2) ~~(2) A change in bed capacity or services that requires review under Regulation .02 of this chapter but involves capital expenditure below the capital expenditure threshold specified in Regulation .01B of this chapter has up to 3 months to obligate 51 percent of the approved capital expenditure, and up to 6 months after the effective date of a binding construction contract to complete the project.~~

~~(g) In a multiphased plan of construction with only one construction contract approved for an existing health care facility, the project has:~~

~~(i) Up to 12 months after Certificate of Need approval to obligate 51 percent of the approved capital expenditure for the entire project;~~

~~(ii) Up to 24 months after the effective date of the binding construction contract to complete the first approved phase of construction; and~~

~~(iii) Up to 24 months after the completion of the previous phase to complete each subsequent approved phase;~~

~~(4) In a multiphased plan of construction with more than one construction contract approved for an existing health care facility, the project holder has:~~

~~(i)~~

(a) Up to 12 months after Certificate of Need approval to obligate 51 percent of the capital expenditure for the first phase of construction; and
~~(ii) Up to 24 months after the effective date of a binding construction contract for the first phase to complete the first approved phase of construction;~~

~~(iii)~~
(b) Up to 12 months after completion of the immediately preceding phase of construction to obligate 51 percent of the capital expenditure for any subsequent approved phase of construction; and

(iv) Up to 24 months after the effective date of a binding construction contract for a subsequent approved phase, to complete that phase;

~~(5) For a multiphased plan of construction, the Commission, upon a showing of good cause by an applicant, may authorize:~~

~~(i) Obligation for each approved phase of construction of a specified portion of the capital expenditure that is less than 51 percent of the approved capital expenditure for the entire project; and~~

~~(ii) Up to 36 months to complete each approved phase; and~~

~~(j) Home health agencies have up to 18 months from the date of the certificate of need to:~~

~~(i) Become licensed and, if applicable, Medicare certified; and~~

~~(ii) Begin operations in the jurisdiction for which the certificate of need was granted.~~
~~(4) If a project is classified as fitting more than one of the categories in §C(3) of this regulation, the category carrying the longer time frame applies.~~

~~(5) For State projects dependent solely on capital funds allocated by the Maryland General Assembly, the requirements of §B(1) of this regulation begin from the date of the Governor's approval of legislative appropriation of funds. If funds are not appropriated by the end of the second year following the granting of the Certificate of Need, the Certificate of Need is void.~~

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~~D. Effective Date of a Certificate of Need, CON or other Commission approval. The effective date of a Certificate of Need, CON or other approval is the date of issuance by the Commission. If a motion action approving the application for the project. If a request for reconsideration is timely filed under Regulation .19, the effective date of the Certificate of Need approval is the date the Commission decides rules on the motion request. The filing of a petition for notice of appeal does not stay enforcement of the Commission decision.~~

~~E. Extension of Performance Requirements.~~

~~(1) A person who holds a Certificate of Need may request only one extension of time, not to exceed 6 months, to meet each applicable performance requirement. The applicant shall provide reasonable assurance that it will meet the performance requirement by the end of the extended period. The Executive Director, for good cause, may approve a requested extension to an applicable performance requirement. The Commission shall fully document an extension approval.~~

~~(2) A request shall be:~~

~~(a) In writing, and~~

~~(b) Received at least 30 calendar days before the date by which the performance requirement is to be completed.~~

~~(3) For purposes of this section, a request is considered to show good cause if it demonstrates that circumstances completely beyond the control of the person who holds the Certificate of Need require the extension. Good cause does not include delays in securing financing.~~

~~F. Failure to Meet Performance Requirements.~~

~~(1) An approved project that fails to fulfill an applicable performance requirement within the specified time period is void. The sponsor of the project may reapply under the Certificate of Need review process, as set forth in Regulations .08—.10 of this chapter, and this resubmitted application shall be considered by the reviewing agencies as a new application.~~

~~(2) Nothing in this section precludes the approval of a project to be undertaken in phases, each of which would be judged in accordance with its own performance requirements, based upon the successive effective dates for each phase, as detailed in the Certificate of Need.~~

~~G. Failure of an applicant to carry out a contract or purchase order that was submitted as evidence of fulfillment of a performance requirement may render the project's Certificate of Need void, as in §F of this regulation.~~

~~H. Grounds for Withdrawal of a Certificate of Need-Commission Approval. The Commission reserves the right to may withdraw a Certificate of Need if the CON or other, Commission approval if it finds that the:~~

~~(1) Applicant~~

~~(1) The holder made a material misrepresentation upon which the Commission relied in granting approving the Certificate of Need application;~~

~~(2) Applicant has~~

~~(2) The holder failed to meet a performance requirement or condition demonstrate sufficient progress in implementing the Certificate of Need project;~~

~~(3) Applicant The holder has failed to obligate or complete an approved project as required by §A of this regulation;~~

~~(4) The provide quarterly reports holder failed to meet a condition in the approval;~~

~~(5) The holder failed to timely provide the annual progress report required under Regulation .13B and C §A of this chapter regulation; or~~

~~(4) Project~~

~~(6) The project differs materially from that approved by the Commission in the Certificate of Need.~~

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F. Notice Before Withdrawal of a ~~Certificate of Need.~~

~~(1) Before withdrawal of a Certificate of Need for failure to fully meet an applicable performance requirement, the~~ CON or Other Commission Approval.

(1) If Commission staff determines that a CON or other Commission approval should be withdrawn, Commission staff shall inform the applicant holder, and the each appropriate local health department, setting forth in writing the reasons for the proposed withdrawal.

(2) This notice shall set forth the right of the applicant holder to submit written argument in support of its position and present oral argument to the Commission, as well as the right to an evidentiary hearing, conducted in accordance with Regulation .11 of this chapter, to show cause why the Certificate of Need should not be withdrawn. The applicant may make a written filing in support of the applicant's position and present oral argument to the full Commission before the Commission takes final action on the notice of withdrawal approval should not be withdrawn.

~~(2)~~

(3) A holder that has failed to demonstrate sufficient progress in project implementation must show that the lack of progress resulted from factors beyond the holder's control.

G. Final action by the Commission withdrawing a ~~Certificate of Need~~ CON or other approval shall:

~~(a)~~

(1) Be in writing;

~~(b)~~

(2) Include findings of fact and conclusions of law; and

~~(c)~~

(3) Be transmitted to the applicant holder, and to the each appropriate local health department within 30 days of the date of action by the Commission.

~~10.24.01.13~~ F. CON Application after Withdrawal of a Prior CON. If a CON or other approval is withdrawn due to lack of sufficient progress in implementing the project, the holder may file an application seeking Commission approval to initiate or complete the previously authorized project, which shall be considered a new application by the Commission.

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13 Conditions of Procedures for Certificate of Need Approval.

A. Approval with Conditions. A Conformance and Certificate of Need may be issued with conditions if the Commission determines that approval with conditions is appropriate.

B. Quarterly Reports:

(1) As a general condition of an approved Certificate of Need, an applicant shall submit to the Commission timely, accurate, and complete quarterly reports of progress in completing the approved project, with a copy to each local health department in the health planning region.

(2) Reports Ongoing Performance Applications

A. Coverage.

(1) A certificate of conformance is required to introduce primary or elective percutaneous coronary intervention services at a hospital.

(2) A certificate of ongoing performance is required and must be periodically renewed to certify that a hospital providing cardiac surgery services or percutaneous coronary intervention services is maintaining an acceptable level of quality and performance in its provision of those services.

(3) A hospital with newly established cardiac surgery services or percutaneous coronary intervention services at an acute general hospital may continue to provide services without a certificate of ongoing performance until the Commission acts on the hospital's first application for a certificate of ongoing performance.

B. Submission of Applications.

(1) An application for a certificate of conformance or a certificate of ongoing performance shall be submitted to the Commission in the form and manner prescribed by the Commission on a quarterly basis, or as otherwise specified by the Commission, beginning 3 months from the date of Certificate of Need approval, and continuing through the applicable time frame of any of the conditions.

(3) Failure to provide these reports may result in withdrawal of the Certificate of Need.

(4) If the review of these periodic reports by the Commission indicates that the project is not progressing satisfactorily, as set out in Regulation .12C of this chapter, or that it is not reasonably attempting to comply with any other specific conditions imposed, the Commission shall initiate the process set forth in Regulation .12I of this chapter for withdrawal of the Certificate of Need.

C. Good Standing. A Certificate of Need is considered to continue in good standing if the applicant provides:

(1) Acceptable quarterly status reports to the Commission and the local health department; and

(2) Written documentation of the fulfillment of applicable performance requirements and conditions

(2) An application shall be submitted in accordance with a published review schedule established by the Commission under §E of this regulation, except that applications to establish both primary and elective percutaneous coronary intervention services based on insufficient access under COMAR 10.24.17.04A(2)(b) may be filed at any time.

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(3) The application, and all information supplementing the application, shall be signed by at least one principal of the applicant, who shall sign a statement as follows: "I solemnly affirm under penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief."

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C. Completeness Review of Certificate of Conformance Applications.

(1) Commission staff shall review a certificate of conformance application for completeness within 15 business days.

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(2) Staff's written request for information to make the application complete shall specify the necessary information. Staff may request additional information beyond that required to make the application complete. The applicant shall provide the completeness and additional information within 15 business days unless an extension is requested and granted.

(3) If Commission staff determines after review of the application and information provided in response to staff's request that the application is complete, staff shall notify the applicant of its determination.

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(4) If ^{time frames}an applicant fails to supply requested information within the specified time limit, staff may dismiss and return the application.

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D. Additional information. Commission staff may:

(1) Request information from an applicant supplementing an application at any time during the review of an application; and

(2) Set reasonable time limits for the applicant to supply the requested information.

E. Notice to the Public.

(1) At least once each year, the Commission staff shall publish in the *Maryland Register* a schedule for reviews of:

(a) Certificate of conformance applications to establish primary or elective percutaneous coronary intervention services; and

(b) Certificate of ongoing performance applications if at least one hospital is required to file an application in the time period covered by the schedule.

(2) The Commission shall publish, on its website, information on the receipt of applications for certificates of conformance and certificates of ongoing performance.

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F. The Commission shall act on an application for a certificate of conformance not later than 150 days after staff determines that the application is complete.

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G. Criteria for Review of Applications. Applicable criteria and standards for certificate of conformance reviews and certificate of ongoing performance reviews are specified in COMAR 10.24.17, the State Health Plan chapter for cardiac surgery and percutaneous coronary intervention services.

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H. Staff Report and Recommendation. Commission staff shall review a certificate of conformance and certificate of ongoing performance applications and prepare a staff report and recommendation that contains the staff's conclusion as to whether the applicant has met each applicable criterion and standard in COMAR 10.24.17.

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I. Exceptions.

(1) An applicant may submit exceptions to a staff report and recommendation and present oral argument on its exceptions to the Commission.

(2) Staff's issuance of a staff report and recommendation shall be accompanied by a notice that specifies the schedule for the submission of exceptions and the date of the Commission meeting at which the Commission shall hear oral argument on exceptions.

(3) Exceptions shall specifically identify each staff conclusion to which exception is taken, citing those portions of the record on which each exception is based.

(4) Exceptions and any response to exceptions shall be limited to 25 pages, double-spaced, excluding attachments.

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(5) Commission staff may file a written response to exceptions and present oral argument at the exceptions hearing.

(6) ~~the~~ Oral arguments on exceptions to the staff report and recommendation and any response shall be limited to ten minutes per argument unless extended by the Chair of the Commission.

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J. Final Decision on an Application for ~~Certificate of Need~~ Conformance.

(1) A final decision on an application for a certificate of conformance shall contain findings of fact and conclusions of law and shall:

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(a) Approve the application;

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(b) Approve the application with conditions; or

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(c) ~~D. Transferability. A Certificate of Need is not transferable.~~

Deny the application.

(2) A certificate of conformance issued by the Commission for an approved application shall specify the period of time for which the initial certificate is effective and the expected date by which the hospital is expected to seek a certificate of ongoing performance for its primary or elective percutaneous coronary intervention services or both.

K. Final Decision on an Application for Certificate of Ongoing Performance.

(1) The Commission's final decision on an application for a certificate of ongoing performance shall contain findings of fact and conclusions of law and shall:

(a) Approve the application;

(b) Approve the application with conditions; or

(c) Deny the application or revoke the Commission's approval for the involved services provided that all the steps in COMAR 10.24.17 including performance of a focused review and an opportunity for agreement upon and completion of a plan of correction have been provided to the hospital.

(2) A certificate of ongoing performance issued by the Commission shall specify the period of time for which the certificate is effective and the expected date by which the hospital is expected to seek a new certificate of ongoing performance for its primary or elective percutaneous coronary intervention services or both, as applicable, or for its cardiac surgery services.

(3) The duration of a certificate of ongoing performance may be extended beyond the renewal deadline, if due to extenuating circumstances, the Executive Director determines an extension is necessary and appropriate, prior to staff producing a written report and recommendation to the Commission regarding the hospital's application for renewal of its certificate of ongoing performance.

L. The decision of the Commission shall be by a majority of the quorum present and voting.

M. The decision of the Commission is subject to judicial review in accordance with Regulation .09F.

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.14 Special Procedures.

A. Determination of Coverage. A project that requires a determination of coverage shall be dealt with in the following manner:

(1) A written request for determination of coverage shall be filed with the Center for Health Care Facilities Planning and Development;

(2) The Executive Director of the Commission shall review the request and act on it within 30 business days of receipt of complete information;

(3) The person requesting the determination shall provide all additional information requested by Commission staff;

(4) The Commission shall notify the person, each appropriate local health department, and each agency responsible under the Department's licensure program for the type of project whether it requires a Certificate of Need or other Commission review;

(5) Commission staff's determination of coverage may be appealed by the requesting party to the Commission by use of a motion filed in accordance with Regulation .10B of this chapter.

(6) The ~~A~~ Executive Director may issue a determination that:

(a) Certificate of Need or other Commission review is not required, with or without conditions; or

(b) Certificate of Need review is required for stated reasons.

B. Declaratory Rulings.

(1) ~~An affected~~ A person uncertain as to how a statute or regulation enforced by the Commission applies to ~~that~~ person or that person's property may file with the Commission a petition for a declaratory ruling in accordance with the procedures in §~~A(2)~~ ~~(1)~~ B of this regulation.

(2) The Commission may decline to issue a declaratory ruling for any of the following reasons:

(a) The petition is not in accordance with this section;

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(b) The petition contains insufficient factual or legal information upon which to base a declaratory ruling; ▲

(c) The petition raises issues adequately addressed in a final decision or regulation of the Commission; ▲

(d) The petition fails to pose a significant issue; ▲

(e) The petition is properly heard as part of an evidentiary hearing; or ▲

(f) A declaratory ruling would not be in the public interest.

(3) Within 15 days of receipt of a petition, the Executive Director shall either assign the petition to the full Commission for a decision or appoint a Commissioner to make a proposed ruling on the petition, which ruling shall be considered by the full Commission.

(4) Within 45 days, or by the second regularly scheduled Commission meeting following the filing of the petition, whichever is later, the Commission shall ~~either rule or decline to rule on the petition. If the petition raises issues requiring further deliberation, the Commission by vote, or~~ may postpone issuing ~~its~~ a formal written declaratory ruling for up to 35 days. ▲

(5) To secure a declaratory ruling, an affected person shall submit a petition for a declaratory ruling that contains the following information:

(a) The petitioner's name, address, and telephone number; ▲

(b) A one or two sentence statement of each question on which a ruling is requested; ▲

(c) A one or two sentence summary of the petitioner's position on each question; ▲

(d) Citation to each provision that the Commission needs to interpret in order to answer each question posed; ▲

(e) A brief statement of each relevant fact; ▲

(f) The petitioner's factual, legal, and policy arguments, referring to documents, affidavits, data, and other relevant information, which shall be appended to the petition, unless the documents are readily accessible to the Commission; and

(g) A statement by the petitioner under penalties of perjury that each fact recited as relevant to the question posed is true to the best of the petitioner's knowledge, information, and belief.

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(6) The Commission shall promptly publish notice of the receipt of a petition in the *Maryland Register*, and shall ~~include~~note the petition ~~under new business~~ on tentative meeting agendas until the Commission acts upon the petition.

(7) ~~In rendering~~ The Commissioner making a ~~declaratory~~ proposed ruling; ~~or~~ the Commission, in addition to considering the materials submitted by the petitioner and comments from staff, may:

(a) Request and receive oral or written statements from any person;

(b) Consider any document, data, study, or other relevant material; or

(c) Require argument on the question on the record, giving the petitioner the opportunity to present argument and to proffer witnesses and documents for the Commission's consideration.

(8) The ~~proposed and final~~ declaratory ruling shall be in writing, and state:

(a) Each question addressed;

(b) The ~~Commission's~~ proposed or final ruling; and

(c) The factual and legal basis for the ruling.

(9) A final declaratory ruling binds the Commission and the petitioner on the facts set forth in the petition, except when this binding effect violates the due process rights of a competing applicant in a comparative review.

(10) The Commission may revoke, alter, or amend a proposed or final declaratory ruling, which may have prospective effect only.

(11) A petitioner may appeal the declaratory ruling as set forth in State Government Article, Title 10, Annotated Code of Maryland.

~~B. Determination of Coverage. A project that requires formal review to determine whether it comes under the law and regulations shall be dealt with in the following manner:~~

~~(1) A request for determination shall be made in writing to the Commission;~~

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~~(2) The Executive Director of the Commission shall review the request and act on it within 30 business days of receipt.~~

~~(3) The requesting party shall provide any additional information requested by the Commission or staff, and the effective date of the Commission's determination shall relate back to the date the Commission received the requested information;~~

~~(4) The Commission shall notify the requesting party, appropriate local health department, and the agencies responsible under the Department's licensure program whether the project requires a Certificate of Need or other Commission review;~~

~~(5) The determination of coverage may be appealed by the requesting party through the procedures set forth in Regulation .09E of this chapter.~~

~~C. The procedures in this regulation provide a means by which an affected person may obtain an appealable decision from the Commission on specific issues. Nothing in this regulation prevents a person from writing the Commission, asking for its opinion or judgment on any matter, and relying on the Commission's response.~~

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15 Commission Approval Required Before Certain Actions.

~~A. Approval of Architectural Plans. Architectural plans and specifications for a project that requires a Certificate of Need may not be approved by the agency responsible for their review under health facility licensure requirements until the project has been issued a Certificate of Need by the Commission.~~

~~B. Approval of State or Federal Grants, Loans, or Mortgage Insurance under Department Administered Programs. Applications by owners or sponsors of projects requiring Commission approval, for federal or State grants, loans, or mortgage insurance under Department administered programs for project construction, modernization, or equipment, may not be officially approved by the administering agency until the applicant and the administering agency have been formally notified of Certificate of Need approval or other action by the Commission.~~

~~C. Signing of Contracts Related to State Capital Improvement. State capital improvement projects for facilities administered by the Department, and requiring approval under the law and these regulations, may not have contracts signed for the development of architectural drawings, construction, or equipment until the Department's administering agency and the State agency responsible for the contracts have been formally notified of Certificate of Need approval or other action by the Commission.~~

~~D~~

A. Obligation of Capital Expenditure.

~~(1) A person may not incur an obligation for a capital expenditure for a project that is subject to review under these regulations until the applicant receives a Certificate of Need CON or other approval required by the Commission approval.~~

~~(2)~~

~~(2) An obligation for capital expenditure is considered to be incurred by or on behalf of a health care facility:~~

~~(a) when a contract, enforceable under State law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset;~~

~~(b) or when a governing body of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or~~

~~(c) in the case of donated property, on the date on which the gift is completed under applicable State law.~~

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B. Obligation of Predevelopment Expenditures. An applicant proposing predevelopment expenditures requiring review under ~~Regulation .02 of this chapter~~ may not enter into a binding contract or other obligation for ~~these~~such activities until the applicant receives a ~~Certificate of Need~~CON or other ~~approval~~ required by the ~~Commission~~ approval.

C. Binding Commitments for Financing. A binding arrangement or commitment for financing a project may not be entered into by an applicant until the applicant receives ~~Certificate of Need~~ CON or other required Commission approval for the project ~~to be financed~~.

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16 Voluntary Withdrawal of an Application.

~~During the review period, an~~

~~An~~ applicant may voluntarily withdraw ~~an~~its application without prejudice ~~prior to~~
final action by the Commission on the application. Written notice of the withdrawal shall
be submitted to the Commission through the ~~Health Facilities Coordination Office,~~Executive
Director. A withdrawn application may be resubmitted at a later date, as a new
application ~~requiring a new letter of intent, new docketing, and review.~~

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17 Project Changes After ~~Certificate of Need~~ Commission Approval.

A. Notification to the Commission:

~~(1) If the project sponsor determines~~ **Filing of Request.** A holder that ~~it~~ desires to change a project that has received ~~Certificate of Need~~ **CON or other Commission** approval, ~~the project sponsor shall notify the following parties in writing of submit a request for the proposed changes:~~

~~(a) The change and supporting documentation to the Commission;~~
~~(b) The copying each local health department within the health planning region of the project and~~

~~(c) In the case of a change in the location or address of a project involving the construction of a new health care facility, to all health care facilities of that type located within the health planning region of the project.~~

~~(2) Notification shall be submitted through the Health Facilities Coordination Office, and shall be supported by appropriate documentation.~~

B. Commission Approval Required Before Project Changes. Any of the following ~~proposed~~ changes that would place the project at variance with its ~~Certificate of Need~~ **CON or other approval** issued under ~~these regulations~~ **this chapter**, including any condition **placed on the approval** issued under Regulation .09D(1)(b) of this chapter, shall ~~receive approval from~~ **be reviewed by** the Commission:

~~(1) Before making a~~ **A** significant change in physical plant design;

~~(2) Before incurring~~ **A** capital cost ~~increases~~ **increase** that ~~exceeds~~ **exceeds** the approved capital cost inflated by an amount determined by applying the ~~Building Cost Index~~ **Hospital Capital Market Baskets** published by ~~IHS Markit~~ **Health Care Cost Review** or other guidance approved by the Commission and posted on the Commission website from the application submission date to the date of the filing of a request for ~~approval of~~ **a project change**;

~~(3) When total projected operating expenses or revenue increases exceed the projected expenses or revenues in the approved Certificate of Need Application, inflated by 10 percent per year;~~

~~(4) Before changing~~ **A change in** the financing mechanisms of the project; ~~or~~

~~(4) A~~ **(5) Before changing** **Change in** the location or address of the project.

C. Impermissible Modifications/Changes. The following proposed ~~modifications~~ **changes** to an approved project require a new ~~Certificate of Need~~ **CON or other appropriate review** and may not be considered by the Commission:

~~(1) Changes in the fundamental nature of a facility or the services to be provided in the facility from those that were approved by the Commission;~~

~~(2) Increases in the facility's total licensed bed capacity or operating room inventory;~~
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(3) Changes in the medical service categories from those provided or approved:

(3) Any change that requires an extension of time to meet the applicable performance requirements specified under Regulation .12 of this chapter, except as permitted under Regulation .12E of this chapter.▲

D. Commission Action.

(1) ~~Changes~~Requested changes subject to review under §B of this regulation shall be reviewed by the Commission.

(2) Within ~~five~~ five days after the ~~Commission's~~ Commission's receipt of a written request to change the address or location of an approved project, ~~which is subject to review under §D(5) of this regulation, the Commission~~ staff shall:

(a) Arrange arrange to publish notice of receipt of the change request in the Maryland Register and one newspaper of general circulation in the appropriate health planning region; ~~and, shall post the notice on its website, and shall provide~~

~~(b) Provide~~ written notice of receipt of the change request to:

(a) Each member of the General Assembly in whose district the relocation is planned;

(b) Each member of the governing body for the jurisdiction in which the relocation is planned; and

(c) The county executive, mayor, or chief executive officer, if any, in whose county or city the relocation is planned.

(3) The Commission shall provide a written notification to the applicant within 45 days of the Commission's receipt of the complete change request that:

(a) The proposed change is approved in whole or part and ~~is~~ incorporated into a modified ~~Certificate of Need~~ CON or other modified approval for the project, ~~with conditions as appropriate; or~~

(b) The proposed change is ~~approved in part or approved with conditions;~~

(c) The proposed change is not approved denied, with explanation: or

(d) The proposed change is of sufficient scope to warrant complete review in accordance with the Certificate of Need review process described in Regulations .08, 10 of this chapter, and may only be considered upon completion of this review.

E. Commission May Seek Advice. The Commission may seek the advice of any agency or person in the performance of a review under this regulation, including each existing health care facility currently operating within the intended service area of the approved or proposed project, and each applicant and interested party in the review that resulted in the grant of the original Certificate of Need.

F. When Commission Action is a New Final Decision. Action taken by the Commission under §D(2)(a) or (b) of this regulation does not constitute a new final decision by the Commission and may not be appealed. Action taken by the Commission following a complete review under §D(3)(d) of this regulation constitutes a new final decision of the Commission.

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18 Review Required Before Licensing or First Use of Project.

A. Request for First Use Review and Approval. Not ~~less~~ fewer than 60 days but not more than 120 days before the first use of any portion of ~~the~~ a facility or service, ~~an applicant developed under a CON or other Commission approval, the holder~~ shall specify the anticipated date for first use and request in writing, through the Center for Health Care Facilities Coordination Office Planning and Development, a final review:

B. Local Health Department.

(1) The local health department may review the project and services in relation to the Certificate of Need ~~and any existing conditions.~~ first use approval. The request shall include:

(1) Documentation of the final cost of the project; and

(2) The local health department shall report its recommendation A description of any differences in writing to the Commission, with a copy to the applicant, as follows:

(a) ~~The project~~ physical plant design, space, or a portion of services in the finished project, continues to conform when compared with the Certificate of Need, and each condition and change approved under Regulation .17 of this chapter, and is recommended for licensure or first use, or both; or

(b) ~~The project, or a portion~~ description of the project, no longer conforms with its Certificate of Need, for reasons stated.

C. Time Frame for Local Health Department Recommendation. In order to be considered reviewed and approved by the Commission, the local health department's recommendation must reach the Commission not less than 20 days before the anticipated date of first use specified by the applicant under §A of this regulation.

D. Commission

B. Action. The Commission shall review the local health department's recommendation and shall ~~act~~ on it ~~within 40~~ Request. Within 30 days of receipt from the local health department. If a local health department of all required information, Commission staff shall issue an approval for first use or a finding that the project does not perform this review, the Commission may use the time allotted to the local health department. Final notification shall be in writing to the applicant, the local health department, and the responsible licensing agencies, in the form of one of the decisions listed in §B of this regulation. The Commission's decision on first use conform to its CON or other Commission approval. Issuance of first use approval is not a new final decision concerning a Certificate of Need CON, and may not be appealed.

E.

C. Nonconformance with Certificate of Need CON or Other Commission Approval. If the Executive Director finds that a project does not conform to its Certificate of Need CON or other approval, the applicant may not proceed to licensure or first use until the Executive Director issues a written finding that the project conforms with its Certificate of Need approval. Based on a finding that a project varies significantly from the project that was granted a Certificate of Need CON or other approval, the Executive Director may invoke the full review process established in Regulations .08—.10 of this chapter in order to reexamine ~~this~~ the project.

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D. Duration of First-Use Approval. First-use approval remains in effect for 90 days. ~~If~~ a project that does not implement put into use within that 90-day period ~~each service for which first~~ use approval was granted, the CON holder shall reapply for first-use approval.

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19 Reconsideration Procedures.

A. Request for Reconsideration. For good cause shown, an aggrieved party may request that the Commission conduct a hearing to reconsider a Commission final decision to grant, to grant with conditions, or to deny a Certificate of Need application ~~of determination of, a request for an exemption from CON review, or other Commission approval issued under Regulation .04 of this chapter.~~ This request shall be in writing and filed with the ~~Commission~~ Center for Health Care Facilities Planning and Development within 15 days of the date upon which the Commission renders its decision.

B. Good Cause. For purposes of this regulation, a request for a reconsideration shows good cause if it:

(1) Presents significant, relevant information which was not previously presented to the Commission and which, with reasonable diligence, could not have been presented before the Commission made its decision;

(2) Demonstrates that there have been significant changes in factors or circumstances relied upon by the Commission in reaching its decision; or

(3) Demonstrates that the Commission has materially failed to follow its adopted procedures in reaching its decision.

C. Notice of Reconsideration Request. ~~Written notice of~~ At least 15 days prior to the date ~~on which the Commission will consider the request for reconsideration request shall be provided at least 15 days before,~~ the Commission ~~considers the request~~ shall provide written notice of the date to the person making the request, each applicant, each interested party, and each relevant local health department. Each interested party may file a written response. ~~A request to present oral arguments shall be made at the time of filing an initial request for reconsideration or a response.~~

D. ~~In considering the reconsideration request, If the Commission shall initially determine whether determines that~~ good cause has been demonstrated. ~~If so,~~ the Commission may reevaluate its previous decision at that time. ~~The Commission may affirm, reverse, or modify its previous decision. Within 30 days,~~

~~Commission Decision Following Reconsideration. If the Commission changes its decision as shall issue a result of the reconsideration request, the Commission shall make~~ new decision containing written findings of fact and conclusions of law stating the basis for its decision ~~within 30 days of its decision on the request.~~

F. ~~Reconsideration Decision Is a New Final Decision. The decision of the Commission on reconsideration is the, which shall be its final decision of the Commission, for purposes of appeal of the decision the purpose of judicial review.~~

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20 Emergency Certificate of Need.

~~A. Commission May Issue~~ The Executive Director may issue an Emergency~~emergency~~ Certificate of Need~~if a~~ under the following circumstances that would otherwise require issuance of a CON:

(1) ~~A~~ situation presents hazards to employees or patients of a health care facility~~or the,~~ and the project required to address the situation would otherwise require CON review;

(2) The closing of a ~~health care~~ facility by State licensing authorities requires changes or adjustments in other facilities to accommodate displaced patients, and the changes or adjustments would otherwise require that these facilities obtain a ~~Certificate of Need~~CON under these regulations~~, the Commission may issue an emergency Certificate of Need.~~; ~~OR~~

(3) A project that would require CON review is necessary to address a public health emergency and cannot be delayed.

~~B. Commission Action~~ The Procedure for an Emergency Certificate of Need.

(1) A health care facility may apply for an emergency CON by sending a signed letter in PDF format by email and hard copy to the ~~Executive Director~~ that contains:

(a) A description of the project for which an emergency CON is sought;

(b) An explanation of the need for emergency action;

(c) The location and current use of the space where the proposed project will be implemented;

(d) The timeframe by which the project can be implemented;

(e) Approximate cost, if known; and

(f) Status of existing unused physical bed space at the health care facility that could quickly be converted to inpatient or resident care to address the emergency.

(2) The applicant shall timely provide additional information requested by Commission ~~is authorized to staff~~.

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C. Commission Action. The Executive Director may grant or deny an emergency Certificate of Need CON after consultation with the chair of the Commission Chairman or the Chairman's designee. Before an emergency Certificate of Need is issued and before licensing action is taken, the Department's and receipt of suitably detailed information from the Office of Health Care Quality shall provide the Commission's Executive Director with suitably detailed written information explaining why regarding the need for emergency action cannot be delayed. If, upon receipt of this information, the Executive Director agrees that the project is needed to address an emergency situation exists, the Executive Director shall issue an emergency Certificate of Need to allow the Office of Health Care Quality to issue an appropriate provisional license. The Executive Director shall notify the Commission of the issuance of the an emergency Certificate of Need at CON shall be on the agenda of the next scheduled Commission meeting for confirmation by the Commission.

D. Duration of Emergency Certificate of Need. The emergency Certificate of Need CON is temporary and may is valid for a period not to exceed 165 days. During The duration of an emergency CON may be extended by the first 30 days of this period; Executive Director for good cause shown by the applicant or at the request of the Secretary.

E. A health care facility ~~shall submit a form~~ that desires to retain the capacity or project approved in an emergency CON shall, at least 30 days before the termination of the emergency CON, file a letter of intent followed by a CON application for a Certificate of Need to the Health Facilities Coordination Office, in accordance with the provisions in Regulation .08 for an unscheduled review. The normal review process and time period set forth in Regulations .08—10 of this chapter applies. apply to the review of a CON application filed after issuance of an emergency CON. This filing deadline may be extended by the Executive Director.

D. Time Frame for Commission Action. Within 150 days of the filing of a complete Certificate of Need application, the Commission shall issue its decision regarding the Certificate of Need.

E. Inapplicability if Capital Expenditure is Involved. An emergency Certificate of Need may only be granted when the emergency change in licensure can be accomplished without a capital expenditure that exceeds the threshold for capital expenditure defined in Regulation .01B of this chapter.

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21 Severability.

If any provision of this chapter is declared void by a court of law, the remainder of this chapter shall be unaffected and of continued force and effect.

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22 Effective Date.

A. A letter of intent or application submitted after the effective date of these regulations is subject to their provisions.

~~B. Projects.~~

B. Determinations for projects.

(1) Upon request, a project that has ~~previously~~ received a Certificate of Need ~~or other Commission~~ approval may be governed by this chapter. ~~In making its determination on a request for conversion, the Commission may, at its discretion, invoke a full review of the project in accordance with this chapter.~~

(2) A request for a determination of coverage under Regulation ~~.14B14A~~ of this chapter, submitted after the effective date of these regulations, is subject to the provisions of this chapter.

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Administrative History

Effective date: July 6, 1972

Regulations .01—.16 amended effective February 4, 1976 (3:3 Md. R. 151)

Regulations .17 and .18 adopted effective February 4, 1976 (3:3 Md. R. 151)

Chapter revised effective March 24, 1978 (5:6 Md. R. 466)

Regulations .01B; .02A, B; .05E; .06B, D—G, K; .07A, B, E; .08A, C; .09A; .11A, D; .15A, B; and .17A, B, D amended as an emergency provision effective July 1, 1978 (5:17 Md. R. 1321); adopted permanently effective December 15, 1978 (5:25 Md. R. 1855)
Regulations .01B; .02A; .06B, F, L; .09D; .11D; .19 amended effective January 25, 1980 (7:2 Md. R. 115)

Regulation .06B amended as an emergency provision effective February 4, 1981 (8:4 Md. R. 334); emergency status expired June 20, 1981 (Emergency provisions are temporary and not printed in COMAR)

Regulation .06M adopted as an emergency provision effective July 1, 1978 (5:17 Md. R. 1321); adopted permanently effective December 15, 1978 (5:25 Md. R. 1855)

Regulations .09E, .11E—G, and .16-1 adopted effective January 25, 1980 (7:2 Md. R. 115)

Regulation .16F repealed effective January 25, 1980 (7:2 Md. R. 115)

Chapter revised as an emergency provision effective March 18, 1983 (10:6 Md. R. 536); emergency status extended at 10:17 Md. R. 1520, 10:22 Md. R. 1964, and 11:5 Md. R. 460 (Emergency provisions are temporary and not printed in COMAR)

Chapter revised effective April 23, 1984 (11:8 Md. R. 714)

Regulation .01 amended and recodified as .01-1, and Preface codified as new Regulation .01 effective November 17, 1986 (13:23 Md. R. 2480)

Regulations .01B, .03D, .07H, and .20B amended as an emergency provision and .03F and .21 adopted as an emergency provision effective August 1, 1985 (12:17 Md. R. 1694); emergency status extended at 12:26 Md. R. 2540; emergency status reapproved effective April 4, 1987 (13:9 Md. R. 1021); emergency status extended at 13:14 Md. R. 1629 and 13:20 Md. R. 2206 (Emergency provisions are temporary and not printed in COMAR)

Regulations .01B, .02A, and .03B amended as an emergency provision and .03F adopted as an emergency provision effective February 28, 1986 (13:6 Md. R. 669) (Emergency provisions are temporary and not printed in COMAR)

Regulations .01B, .06C, E, .07A—D, F, P, .11, and .23 amended as an emergency provision and .06F adopted as an emergency provision effective March 15, 1986 (13:8 Md. R. 890) (Emergency provisions are temporary and not printed in COMAR)

Regulations .01-1, .03, .06, .07, and .11 amended as an emergency provision effective July 16, 1987 (14:16 Md. R. 1767); emergency status extended at 14:18 Md. R. 1962 (Emergency provisions are temporary and not printed in COMAR)

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Regulations .01-1, .03, .06, .07, .11 and .23 amended as an emergency provision effective September 23, 1987 (14:21 Md. R. 2217); adopted permanently effective February 8, 1988 (15:3 Md. R. 304)

Regulations .01-1, .03, .06, .07, .09, .11, .15—.18, and .20 amended as an emergency provision effective March 9, 1989 (16:7 Md. R. 802); emergency status extended at 16:20 Md. R. 2178 and 17:3 Md. R. 295 (Emergency provisions are temporary and not printed in COMAR)

Regulation .01-1 amended effective February 13, 1995 (22:3 Md. R. 154)

Regulation .01-1B amended effective April 6, 1987 (14:7 Md. R. 831); October 30, 1989 (16:21 Md. R. 2262); March 19, 1990 (17:5 Md. R. 638)

Regulation .02A—C amended effective November 17, 1986 (13:23 Md. R. 2480); March 19, 1990 (17:5 Md. R. 638)

Regulation .02D amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .03 amended effective November 17, 1986 (13:23 Md. R. 2480); March 19, 1990 (17:5 Md. R. 638)

Regulation .03G—I amended effective February 13, 1995 (22:3 Md. R. 154)

Regulation .03H adopted effective April 6, 1987 (14:7 Md. R. 831)

Regulation .03K adopted effective June 13, 1988 (15:12 Md. R. 1447)

Regulation .03L adopted effective October 30, 1989 (16:21 Md. R. 2262)

Regulation .06 amended effective November 17, 1986 (13:23 Md. R. 2480)

Regulation .06C amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .07 amended effective November 17, 1986 (13:23 Md. R. 2480); April 6, 1987 (14:7 Md. R. 831); March 19, 1990 (17:5 Md. R. 638); June 6, 1994 (21:11 Md. R. 951)

Regulation .08C amended effective November 17, 1986 (13:23 Md. R. 2480); August 3, 1992 (19:15 Md. R. 1390)

Regulation .09A amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .11 amended effective November 17, 1986 (13:23 Md. R. 2480)

Regulation .11C amended effective February 13, 1995 (22:3 Md. R. 154)

Regulation .11E amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .15 amended effective March 19, 1990 (17:5 Md. R. 638); October 10, 1994 (21:20 Md. R. 1732)

Regulation .16E amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .17A amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .18 amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .20A amended effective March 19, 1990 (17:5 Md. R. 638)

Regulation .20B amended effective November 17, 1986 (13:23 Md. R. 2480)

Regulation .21 amended effective November 17, 1986 (13:23 Md. R. 2480)

Regulation .23 amended effective November 17, 1986 (13:23 Md. R. 2480)

Regulation .23B amended effective April 6, 1987 (14:7 Md. R. 831)

Regulation .23E, F amended effective February 13, 1995 (22:3 Md. R. 154)

Annotation: COMAR 10.24.01.06 cited in Doctors' Hospital v. Health Resources Planning Commission, 65 Md. App. 656 (1986)

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Annotation: COMAR 10.24.01.07 cited in Sinai Hospital v. Health Resources Planning Commission, 306 Md. 472 (1986)

Annotation: COMAR 10.24.01.07 cited in Perini Services Inc. v. Health Resources Planning Commission, 67 Md. App. 189 (1986)

Regulations .01—.23 repealed and new Regulations .01—.22 adopted effective November 6, 1995 (22:22 Md. R. 1658)

Regulation .01B amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)

Regulation .01B amended effective August 21, 2000 (27:16 Md. R. 1523); February 5, 2001 (28:2 Md. R. 100); November 24, 2003 (30:23 Md. R. 1652); April 11, 2005 (32:7 Md. R. 680); October 23, 2006 (33:21 Md. R. 1675); April 9, 2007 (34:7 Md. R. 699)

Regulation .02 repealed and new Regulation .02 adopted effective August 21, 2000 (27:16 Md. R. 1523)

Regulation .02 amended effective April 11, 2005 (32:7 Md. R. 680)

Regulation .02A amended effective February 5, 2001 (28:2 Md. R. 100)

Regulation .03 repealed and new Regulation .03 adopted effective August 21, 2000 (27:16 Md. R. 1523)

Regulation .03 amended effective August 21, 2000 (27:16 Md. R. 1523); April 11, 2005 (32:7 Md. R. 680)

Regulation .03A amended effective November 24, 2003 (30:23 Md. R. 1652)

Regulation .03B, J amended effective October 23, 2006 (33:21 Md. R. 1675)

Regulation .03I amended effective April 10, 2006 (33:7 Md. R. 672)

Regulation .03K amended effective April 9, 2007 (34:7 Md. R. 699)

Regulation .04 repealed and new Regulation .04 adopted effective August 21, 2000 (27:16 Md. R. 1523)

Regulation .04 amended effective April 11, 2005 (32:7 Md. R. 680)

Regulation .05 repealed and new Regulation .05 adopted effective April 6, 1998 (25:7 Md. R. 527)

Regulation .05 amended effective April 11, 2005 (32:7 Md. R. 680)

Regulation .07 amended effective April 11, 2005 (32:7 Md. R. 680)

Regulation .08 amended effective April 11, 2005 (32:7 Md. R. 680)

Regulation .08C, E amended effective April 10, 2006 (33:7 Md. R. 672)

Regulation .08D, F amended effective April 9, 2007 (34:7 Md. R. 699)

Regulation .08E, G amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)

Regulation .09 amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)

Regulation .09 amended effective April 11, 2005 (32:7 Md. R. 680); April 9, 2007 (34:7 Md. R. 699)

Regulation .09A amended effective April 10, 2006 (33:7 Md. R. 672)

Regulation .09C amended effective November 24, 2003 (30:23 Md. R. 1652)

Regulation .09D amended effective April 10, 2006 (33:7 Md. R. 672)

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Regulation .10 amended as an emergency provision effective November 9, 1995 (22:24 Md. R. 1874); amended permanently effective March 11, 1996 (23:5 Md. R. 379)
Regulation .10 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .11 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .12 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .12C amended effective November 24, 2003 (30:23 Md. R. 1652); April 9, 2007 (34:7 Md. R. 699)
Regulation .13 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .13B amended effective May 5, 1997 (24:9 Md. R. 657)
Regulation .14 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .15 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .16 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .17 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .18 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .19 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .20 amended effective April 11, 2005 (32:7 Md. R. 680)
Regulation .20E amended effective April 9, 2007 (34:7 Md. R. 699)
Regulation .22 amended effective April 11, 2005 (32:7 Md. R. 680)

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